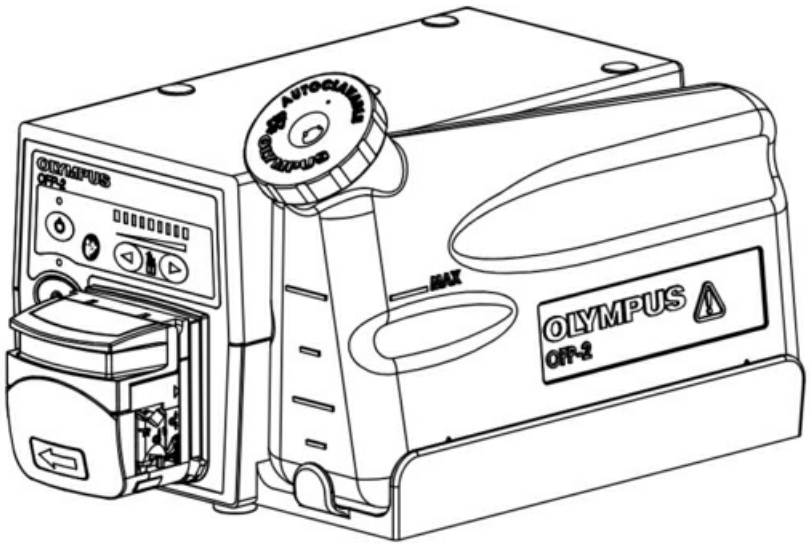
OLYMPUS OFP-2 INSTRUCTIONS MANUAL



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OLYMPUS®

INSTRUCTIONS

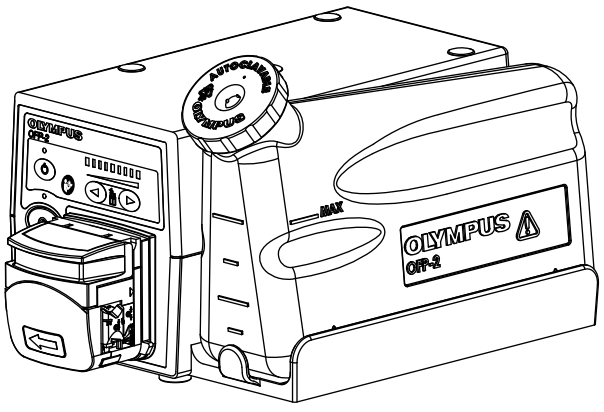
OLYMPUS FLUSHING PUMP

OFP-2

and

WATER CONTAINER

MAJ-1603



USA: CAUTION: Federal law restricts this device to sale by or on the order of a physician.

CE 2797

Contents

Important Information — Please Read Before Use

Intended purpose

Intended use and indications

The Olympus OFP-2 Flushing Pump is a peristaltic pump intended to supply fluid to compatible Olympus endoscopes or endotherapy devices for irrigation of the gastric and colonic mucosa during endoscopic or endotherapeutic procedures, allowing improved visualisation, diagnosis and treatment.

The pump can also assist in the use of transendoscopic ultrasound probes by rapidly filling the organ to be examined.

Contraindications

There are no known contraindications.

Patient target group

Not dedicated to any patient population.

Intended user

- **Medical use**

Only for use by a qualified physician or a healthcare professional in an adequate medical environment. These instructions for use do not explain or discuss clinical procedures.

- **Reprocessing**

Reprocessing of reusable products may only be performed by qualified hygiene personnel.

- **Repair**

Repair of the product may only be performed by trained qualified servicing personnel that has been authorized by Olympus. Otherwise, Olympus cannot be held responsible for the safety and performance of the product.

Clinical benefits

The clinical benefit of the device lies in its functionality as described by its intended purpose.

Contact

Manufacturer

KeyMed (Medical and Industrial Equipment) LTD
KeyMed House, Stock Road,
Southend-on-Sea, Essex SS2 5QH
United Kingdom
www.olympus.com
concerns@olympus.co.uk

Incident reporting

- **European Union**

If a serious incident occurs with the device, report it to the manufacturer and the relevant national authority.

- **Eurasian Economic Union**

If a serious incident occurs with the device, report it to the manufacturer and the relevant national authority.

- **Other regions**

If a serious incident occurs with the device, report it to the manufacturer and/or the relevant national authority according to national legislation.

Applicability of endoscopy and endoscopic treatment

If there is an official standard on the applicability of endoscopy and endoscopic treatment that is defined by the hospital's administration or other official institutions such as academic societies on endoscopy, follow that standard. Before starting endoscopy and endoscopic treatment, thoroughly evaluate its properties, purposes, effects, and possible risks (their natures, extent and probability). Perform endoscopy and endoscopic treatment only when its potential benefits are greater than its risks.

Fully explain to the patient the potential benefits and risks of the endoscopy and endoscopic treatment as well as any examination/treatment methods that can be performed in its place, and perform the endoscopy and endoscopic treatment only after obtaining the consent of the patient.

Even after starting the endoscopy and endoscopic treatment, continue to evaluate the potential benefits and risks, and immediately stop the endoscopy/ treatment and take proper measures if the risks to the patient become greater than the potential benefits.

Instruction manual

This instruction manual contains essential information on using this equipment safely and effectively. Before use, thoroughly review *this* manual and the *manuals of all equipment* which will be used during the procedure and use the equipment as instructed.

If you have any questions or comments regarding the information in this manual, please contact Olympus. These instructions should be retained for reference during the life of the product.

Instrument compatibility

Refer to the “System chart” in the Appendix to confirm that this instrument is compatible with the ancillary equipment being used. Using incompatible equipment can result in patient injury and/or equipment damage. This instrument complies with the EMC standard for medical electrical equipment; IEC 60601-1-2:2014 Edition 4. However, when connecting to an instrument that complies with earlier editions of this standard, the whole system complies with that edition.

Repair and modification

This equipment does not contain any internal user-serviceable parts. Do not disassemble, modify or attempt to repair it; patient or user injury and/or equipment damage can result.

Some problems that appear to be malfunctions may be correctable by referring to “Troubleshooting” on page 54.

If the problem cannot be resolved using the information in “Troubleshooting” on page 54, please contact Olympus.

Signal words

The following signal words are used throughout this manual:

WARNING

Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION

Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices or potential equipment damage.

NOTE

Indicates additional helpful information.

Warnings and cautions

Follow the warnings and cautions given below when handling this equipment. This information is to be supplemented by the warnings and cautions given in each chapter. The OFP-2 is EMC-tested (electromagnetic compatibility) in conformity with the requirements of IEC 60601-1-2:2014 Edition 4 and meets the general electrical safety requirements of IEC 60601-1:2005 + A1:2012 Edition 3.1 (equivalent to EN 60601-1:2006 + A1:2013).

WARNING

- Explosion hazard - never install or use the OFP-2 within the zone of risk of flammable gases.
- The OFP-2 should only be used in a medical facility under the direction of a trained physician.
- For additional information, refer to the appropriate ‘instructions for use’ for the equipment and consumables used in conjunction with the OFP-2.
- The operator must assess the condition of the patient and use clinical judgement to set the flow rate from the pump to a suitable level to avoid patient trauma. The flow rate should always be checked at the start of the procedure and be increased/decreased progressively to a level commensurate with the clinical condition of the patient and degree of washing required.
  - Note that this unit can deliver flow rates through the instrument channel of the endoscope in excess of that which can be delivered when using a 50ml syringe.
- The water container and cap were not cleaned, disinfected, or sterilized before shipment. Before using the water container and the cap for the first time, reprocess these according to “Operating instructions” on page 33.
- For endoscope instrument channel flushing, use only the MAJ-1607 instrument channel water tube with MAJ-1606 instrument channel adaptor, otherwise patient safety may be compromised or damage to the pump may occur.
- For endoscope auxiliary channel flushing, use the MAJ-1608 or MAJ-1651/2 auxiliary channel water tube with MAJ-855 auxiliary water tube to connect the OFP-2 to the endoscope, otherwise patient safety may be compromised or damage to the pump may occur.

- For EndoTherapy accessory channel flushing, use the MAJ-1681 or MAJ-1682 accesssory port tubes, otherwise patient safety may be compromised or damage to the pump may occur.
- When flushing with ø2.0 to ø2.2mm instrument channel videoscopes, remove the EndoTherapy instrument from the MAJ-1606. Otherwise, leakage or spraying of potentially contaminated fluid may occur. With an EndoTherapy instrument inserted in the instrument channel, do not flush and extract at the same time, as there is a potential risk of spraying.

WARNING

- If high flow rates are required while accessory tools are inserted in the endoscope instrument channel, there is an increased risk of fluid leakage. Therefore, the user should slow the pump speed to reduce any fluid loss, or take precautionary measures to ensuring there is no danger to users, patients or equipment.
- Note that the luer lock connector on the MAJ-855 includes a one-way valve to prevent backflow - do NOT use the MAJ-855 without this connector in place, or water tube, water container and water contamination may result.
- Confirm that the wall power outlet has adequate electrical capacity to power the equipment connected to it. Failure to do so may cause fire or power failure to all equipment connected to the same power circuit.
- To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- The water tube MAJ-1608 must be replaced daily - failure to do so may lead to patient infection and a reduction in equipment performance.
- When removing the MAJ-855 from the MAJ-1608, firstly ensure the pinch clamp is always closed to prevent fluid leakage when disconnection is made, to avoid a slip hazard.
- Clean, disinfect or sterilize the MAJ-855 following each use according to the manufacturer’s instructions supplied with the product and instructions of the endoscope.
- The MAJ-1606, MAJ-1607, MAJ-1652, MAJ-1681 and MAJ-1682 are single use, disposable items, and must be replaced after each patient. Do not reuse or attempt to resterilize them. Failure to do so may lead to risk of cross-infection.
- The Remote Control socket on the rear of the unit is for the exclusive connection of compatible Olympus equipment, as shown in the "System chart" in the Appendix. Connection to other equipment could compromise the safety of the system.
- The operator should not touch the Remote Control socket whilst simultaneously touching the patient.
- Do not modify this equipment.

- The Olympus OFP-2 is a medical device that requires safety measures in regards to EMC. The device must be installed and put into operation in accordance with the EMC information listed in “Operating instructions” on page 33 of this document.
- Always use the supplied power cord. Use of any other power cord can cause a malfunction of the device or the power cord to burn. Additionally, the supplied power cord is for exclusive use with the device it has been provided with and must not be used with other devices.

CAUTION

- Do not use sterile accessories if the packaging is damaged or opened.
- Use only in conjunction with OLYMPUS gastrointestinal/colono/ ultrasound endoscopes of EVIS EXERA/EXERA II/EXERA III/LUCERA/ LUCERA ELITE/EUS series and compatible EndoTherapy instruments.

CAUTION

- Check the “USE BY” date of all accessories as indicated on the packaging label. Do not use any accessories beyond the specified “USE BY” date.
- Do not allow the water container to run dry, otherwise air will be supplied to the patient causing discomfort.
- To prevent free-flow of water to the patient, do not open the pump head lever when the OFP-2 is connected to an endoscope which is inserted into the patient. Ensure the OFP-2 is positioned below patient level.
- If any section of tube from the pump to the water container is blocked or kinked, the flow rate will be noticeably reduced. Check the tube for kinks or blockages, and should the slightest irregularity be suspected - do not use.
- If a kinked or damaged tube causes the pump head to jam, the unit will sense the increased load on the motor and shut down. Refer to “Operating instructions” on page 33.
- Should the OFP-2 be operated with a blocked endoscope or MAJ-1608 with its tube pinch clamp closed, damage to the endoscope and/or water tube may occur. In this event, care must be taken when disconnecting the fluid path as the system may be pressurised. To assist in depressurising the system, the pump head should be opened to allow water back into the bottle. This must only be carried out with the endoscope removed from the patient.
- In the event of tube pinch clamp failure when using MAJ-1608, drain the fluid back to the source by opening the pump head and lifting the connector end above the water level in the fluid container/ bottle before disconnection. The tube and clamp should be replaced if any fault is detected.
- Replace the tube and clean and sterilize the water container and water container cap before the unit is reused.

- Inspect the MAJ-855 for obvious signs of wear or damage, and should the slightest irregularity be suspected - do not use. Replace in accordance with its instructions for use.
- Before each use, inspect the water container and cap for obvious signs of wear or damage and should the slightest irregularity be suspected - do not use.
- Always remove and empty the water container before moving the equipment. Care should be taken to obtain a firm grip underneath the body of equipment before moving. The water container must never be used as a hand hold or carrying handle.
- Do not remove the water container while the pump is active. Ensure that the pump is in the ‘OFF‘ position before removing or replacing the tube sets.
- Store and use the OFP-2 within the environmental conditions described in “Specification” on page 51; failure to do so may lead to equipment malfunction or failure.

CAUTION

Only use replacement parts as specified in “Spares” on page 50. Failure to do so may lead to equipment malfunction or failure.

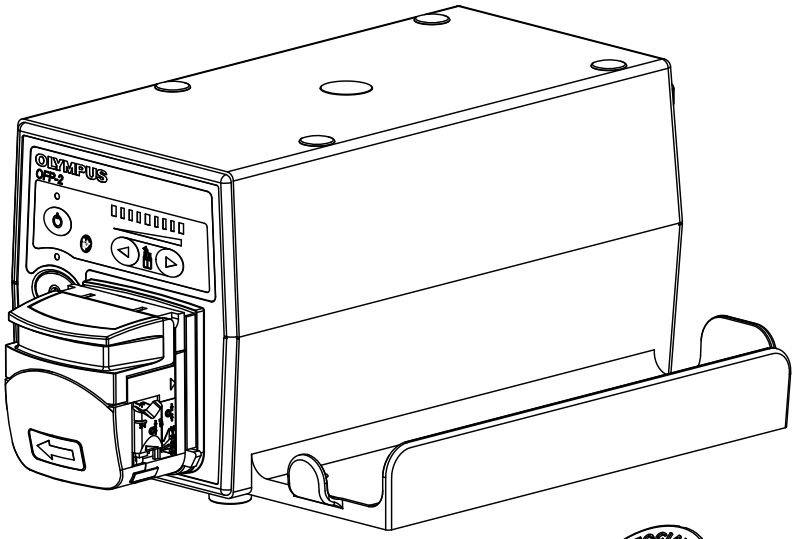
- In accordance with the instructions supplied with the endoscope, ensure that the auxiliary water channel or instrument channel is free from blockages before starting a procedure.
- Personal protective equipment should be used in accordance with local or national clinical guidelines.
- In the event of equipment failure, an alternative method of irrigation should be used in accordance with the endoscope instruction manual.
- During use, do not obstruct the vents in the base and rear of the OFP-2
- The OFP-2 should not be positioned where the water container is directly exposed to heat emitted from adjacent equipment, otherwise fluid in the container may become hot after a period of time and scald the patient.
- Before the procedure begins when using the MAJ-1681, ensure the water container is filled with sterile saline.
- Activation of the pump while the tubing/EndoTherapy accessory is connected to the OFP-2 but not inserted into an endoscope may result in potentially contaminated fluid being pumped from the end of the system and coming into contact with the floor, electrical equipment and people in the area.
- If a water tube is installed incorrectly and becomes damaged, the water tube set must be discarded and replaced.

- Prior to each use, ensure the tube connections are secure, watertight and routed to eliminate potential flow restrictions caused by, but not limited to, tube kinking or accidental tube compression. Keep the tubing clear of the patient at all times. In the event of entanglement, stop the procedure and re-route the tubing.
- Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in their accompanying documents.
- It should be noted that portable and mobile RF communications equipment can affect medical electrical equipment.
- The use of accessories and cables other than those specified may result in increased emissions or decreased immunity of the medical electrical equipment or system.
- Ensure that the OFP-2 is not used adjacent to or stacked with other equipment (other than components of the OFP-2 or the endoscopy system) to avoid electromagnetic interference.
- When the OFP-2 is used in close proximity to other equipment, the medical electrical equipment or system should be observed to verify normal operation in the configuration in which it will be used.

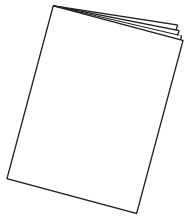
Chapter 1 Checking the Package Contents

1.1 Checking the OFP-2 package contents

Unpack the OFP-2 and associated items from the packaging and confirm that all items in the standard set are present. Contact your Olympus service centre or nearest Olympus office if any parts are damaged or missing.



Olympus Flushing Pump OFP-2



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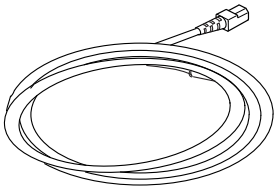
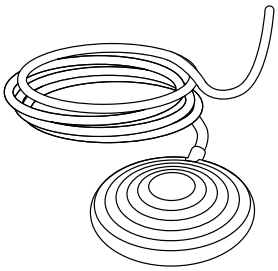
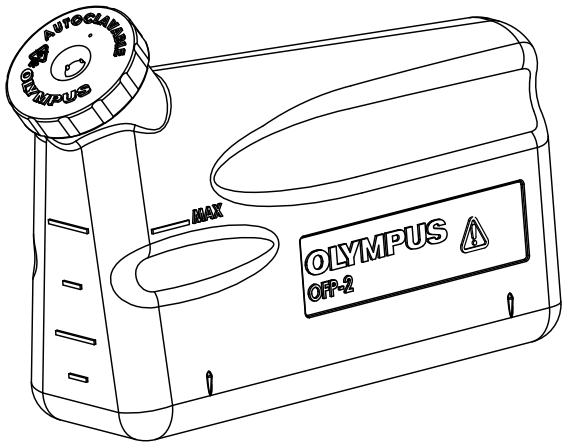


Power cord



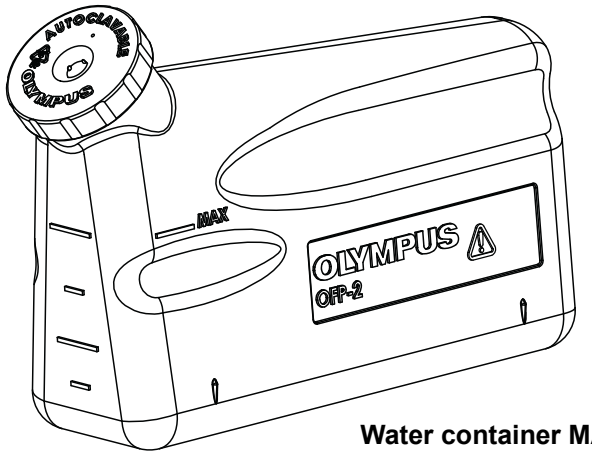
Foot switch



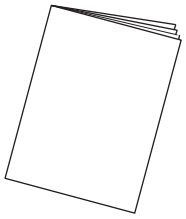
Water container MAJ-1603

1.2 Checking the MAJ-1603 package contents (if purchased separately)

Unpack the MAJ-1603 and associated items from the packaging and confirm that all items in the standard set are present. Contact your Olympus service centre or nearest Olympus office if any parts are damaged or missing.



Water container MAJ-1603 (3 pcs)



Instruction manual

1.3 Consumable components

Product	Description
MAJ-1606	Instrument channel adaptor (pack of 100)
MAJ-1606	Instrument channel adaptor (pack of 10)
MAJ-1607	Instrument channel water tube (pack of 50)
MAJ-1607	Instrument channel water tube (pack of 10)
MAJ-1608	Auxiliary channel water tube (pack of 50)
MAJ-1608	Auxiliary channel water tube (pack of 10)
MAJ-1651*	Auxiliary channel water tube set (pack of 10) supplied sterile
MAJ-1652*	Auxiliary channel adaptor (pack of 100) supplied sterile
MAJ-1681	Accessory port tube with bottle cap (pack of 10) supplied sterile
MAJ-1682	Accessory port tube with saline spike (pack of 10) supplied sterile
MAJ-2207**	Irrigation Tubing with CO2 (pack of 10) supplied sterile
MAJ-2208**	Irrigation Tubing with CO2 (pack of 10) supplied sterile
MAJ-2209**	Irrigation Tubing with Air (pack of 10) supplied sterile
MAJ-2210**	Irrigation Tubing with Air (pack of 10) supplied sterile

* The MAJ-1651/1652 is an alternative to the MAJ-1608 and MAJ-855 and is supplied sterile. Please refer to the MAJ-1651/1652 instructions for use for installation.

** Please refer to MAJ-2207/2208/2209/2210 instructions for use for installation.

Please specify the product and quantity when purchasing.

1.4 Accessories

Product	Description
MAJ-1603	Water container (pack of 3)
MAJ-855	Auxiliary water tube
MAJ-920	Remote control cable

Chapter 2 Nomenclature and Functions

2.1 Front panel

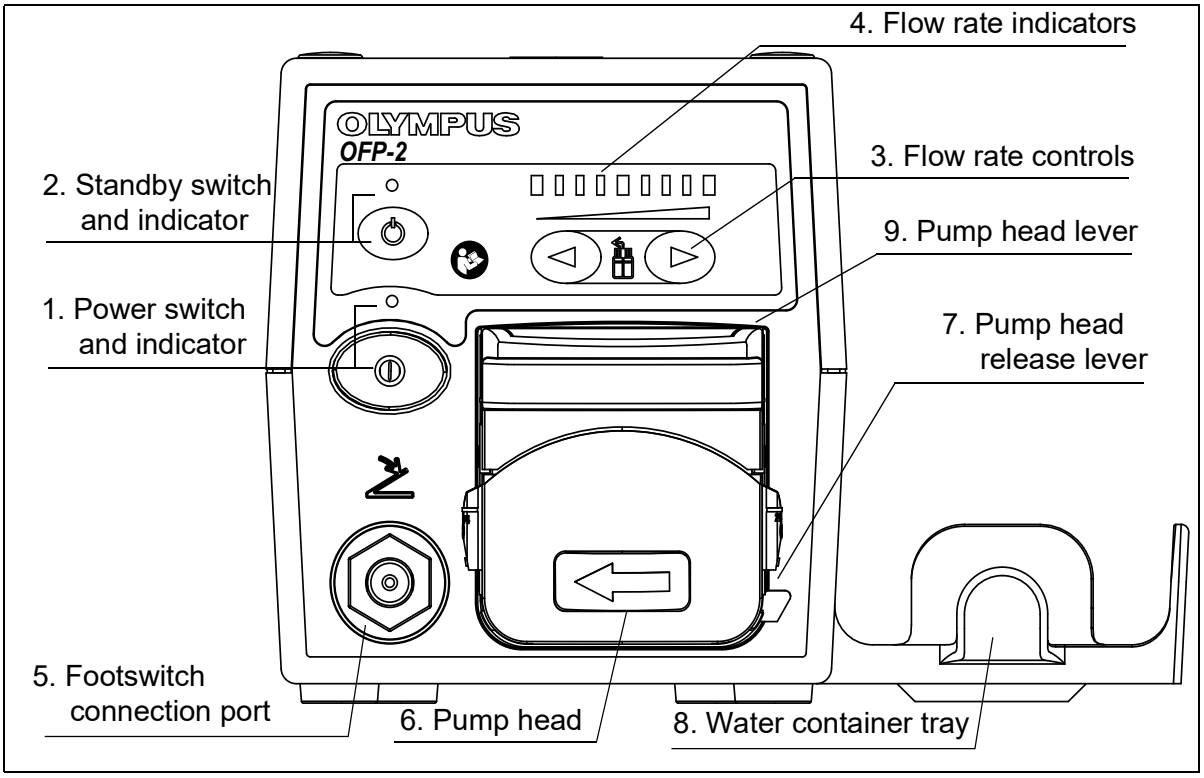


Figure 2.1

1. **Power switch and indicator**
   This switch is pressed to turn the power ON or OFF. The power indictor will illuminate green when power is ON.
2. **Standby switch and indicator**
   The standby switch changes the unit from “standby mode” to “run mode”. The standby indicator illuminates green when the unit is in “run mode” and amber when in “standby mode”. The unit goes into "standby mode" when the pump head lever is open.
3. **Flow rate controls**
   Increases “▶” or decreases “◀” the flow of water to the endoscope or the EndoTherapy device by pressing the ▶ and ◀ switches as required. The flow rate is stored in memory until the unit is switched OFF.

4. **Flow rate indicators**
   Displays the current flow rate setting.
5. **Footswitch connection port**
   Allows connection of the footswitch to control pump operation.
6. **Pump head**
   The rotary type peristaltic pump comprises three rollers which transfers water from the water container to the endoscope or the EndoTherapy device.
7. **Pump head release lever**
   Allows the pump head to be removed from the unit.
8. **Water container tray**
   Supports the water container when fitted.
9. **Pump head lever**
   Open and close when inserting or removing the tube in the pump head.

2.2 Rear panel

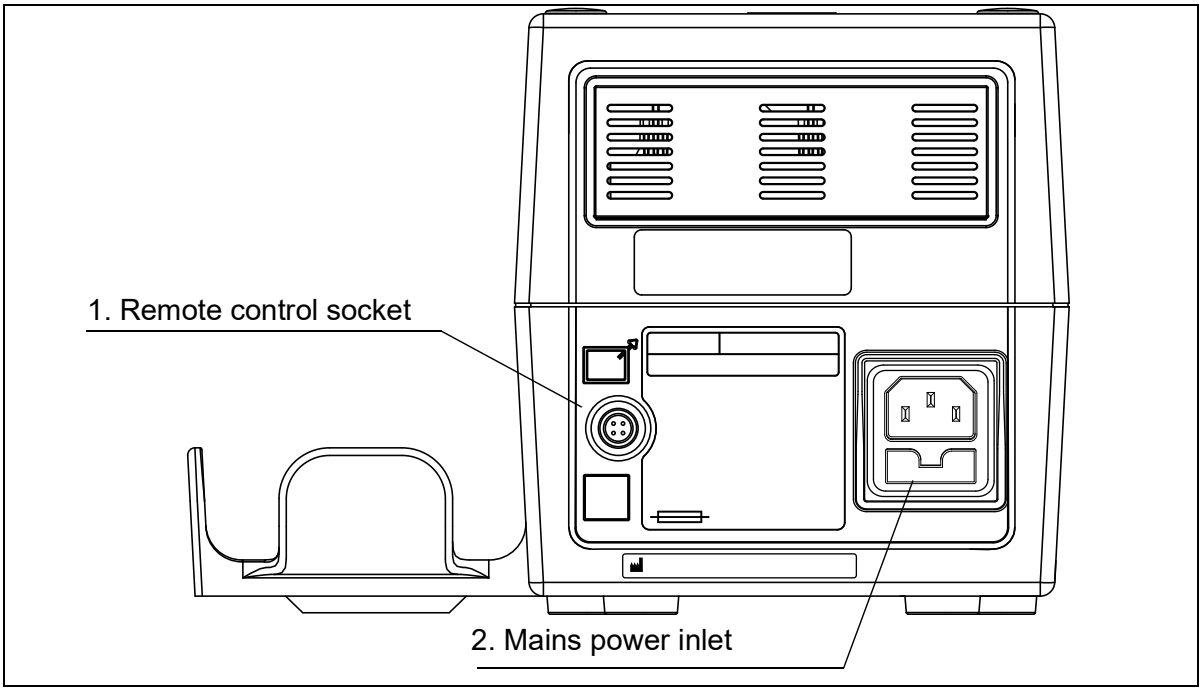


Figure 2.2

1. **Remote control socket**
   Enables the OFP-2 to be remotely controlled from other compatible Olympus equipment via the MAJ-920 remote control cable.
2. **Mains power inlet**
   Connects the OFP-2 to the mains power supply using the IEC power cord provided. The Mains power inlet is fitted with two integral fuses.

2.3 Symbols and labels

UDI label

UNIQUE DEVICE IDENTIFICATION

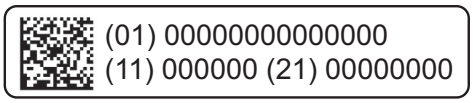
A label required by some countries' regulations regarding identification of medical device also known as Unique Device Identification.

The following information is being coded in the 2-dimensional barcode (GS1 Data Matrix);

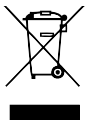
(01) 14-digit GS1 Global Trade Item number.

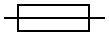
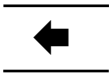
(11) 6-digit date of manufacture.

(21) 8-digit serial number.



Symbol	Description	Source
REF	Catalog number	ISO 15223-1
SN	Serial number	ISO 15223-1
LOT	Batch code	ISO 15223-1
	Date of manufacture	ISO 15223-1
	Manufacturer	ISO 15223-1
	Use-by date	ISO 15223-1
Rx Only	Federal (USA) law restricts this device to sale by or on the order of a physician	FDA
CE 2797	CE marking indicating that the device is in conformity with the applicable requirements set out in applicable European Union harmonization legislation	MDR (EU) 2017/745
	Temperature limit	ISO 15223-1

	Humidity limit	ISO 15223-1
	Atmospheric pressure limit	ISO 15223-1
	General warning sign	ISO 7010_W001
	Caution, consult accompanying documents	ISO 7000
	Fragile, handle with care	ISO 15223-1
	Keep away from sunlight and heat	ISO 15223-1
	Keep dry	ISO 15223-1
	Stacking limit by number	ISO 7000
	This way up	ISO 7000
	In accordance with European Directive on Waste Electrical and Electronic Equipment (WEEE), this symbol indicates that the product must not be disposed of as unsorted municipal waste, but should be collected separately	European Directive 2002/96/EC
	Stand-by	IEC 60417-5009
	Mains power ON/OFF switch	IEC 60417-5010

	Foot switch	IEC 60417-5114
	Alternating current	IEC 60417
	Fuse	IEC 60878
	Risk of trapping hand/finger	Manufacturer
	To indicate the control for changing over to remote control	IEC 60878
	Direction of flow	Manufacturer
	PSE EMC Compliance	METI-PSE regulations (Electrical Appliances and Materials Safety Act) Japan
	Refer to instructions for use	ISO 7010-M002
	Consult instructions for use	ISO 15223-1
	Indicates the unit has been independently assessed for compliance with AAMI ES60601-1 and CSA standards	EN 60601

	Unit complies with China RoHS 2 requirements	China RoHS 2 – Management methods for the Restriction of the Use of Hazardous Substances in Electrical and Electronic Products, January 2016
	Recycling polypropylene	ASTM D7611-13
	This is a medical device according to MDR (EU) 2017/745	Manufacturer
	eIfU - Instructions for use available online	ISO 15223-1
	Translation	ISO 7000
	Authorized representative in the European Community / European Union	ISO 15223-1
	UKCA Marking indicating that the device is in conformity with the applicable requirements set out in the applicable UK legislation.	MHRA
	Importer	ISO 7000

Chapter 3 Preparation for use

1. Unscrew the cap from the water container and clean and sterilize both items before use (see “Cleaning and Sterilizing” on page 38).

WARNING

The water container and cap were not cleaned, disinfected, or sterilized before shipment. Before using the water container and the cap for the first time, reprocess these according to “Cleaning and Sterilizing” on page 38.

2. Position the mobile workstation on a flat level surface and apply both castor brakes. If the workstation has a rear panel, remove it.

NOTE

Refer to the workstation instructions for rear panel removal/replacement and manoeuvring details.

3. Referring to Figure 3.1, place the OFP-2 on the base shelf of the mobile workstation to the right hand side, allowing room for a suction pump to be placed on the left.

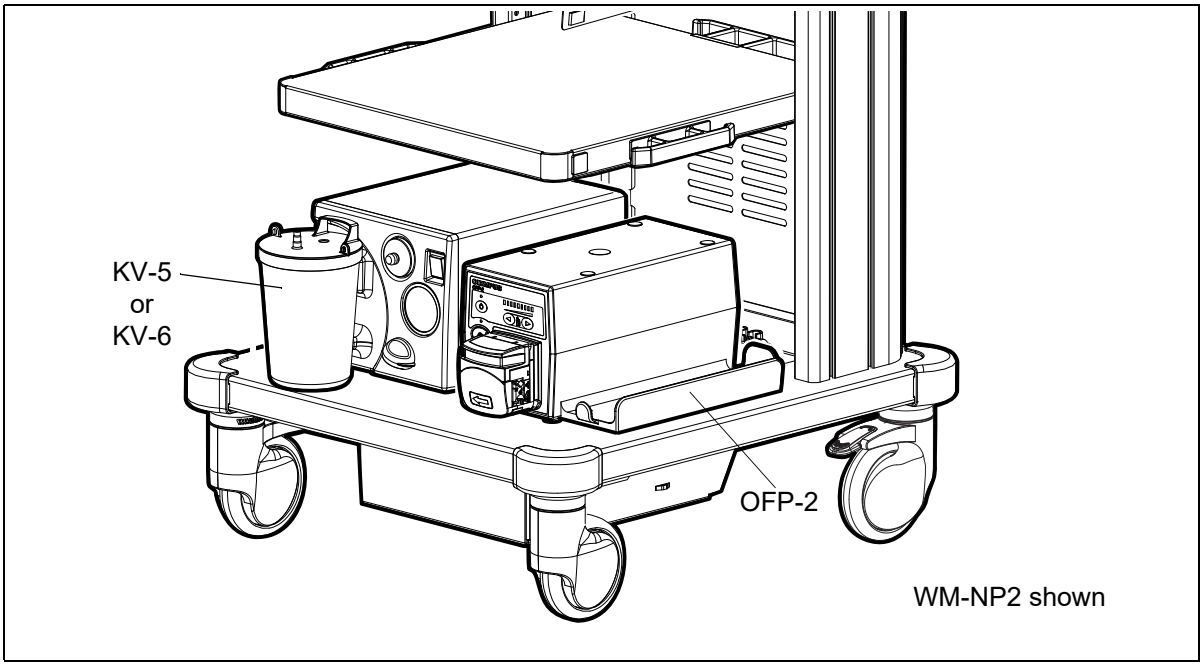


Figure 3.1

WARNING

The OFP-2 should only be used in conjunction with a KV-5/KV-6 or other suitable sources of medical suction as specified in the endoscope instruction manual.

4. Fill the water container up to the max fill line with sterile fluid (deaerated water when using with ultrasound products) and secure the cap.
5. Place the water container into position on the OFP-2.

CAUTION

- For endoscope, use only sterile water. For EndoTherapy device, use only sterile saline. Sterile water should be degassed if the OFP-2 is to be used with an ultrasound endoscope. Use of non-sterile fluid may cause an infection risk to the patient.
- The water container should always be removed from the OFP-2 and filled away from the workstation.
- To prevent spillage, take care not to tilt the container too far when filled or when placing it on the water container tray. The water container will leak fluid from the hole in the cap when tilted beyond 15°.
- To prevent fluid exuding from the cap:
  - Take care not to squeeze the filled water container when transferring back to the OFP-2.
  - Take care when placing the filled water container into the OFP-2 tray.
  - Do not fill the water container past the “MAX” fill line.

6. Insert the footswitch tube into the footswitch connection port on the front panel (Figure 3.2) and place the footswitch on the floor.

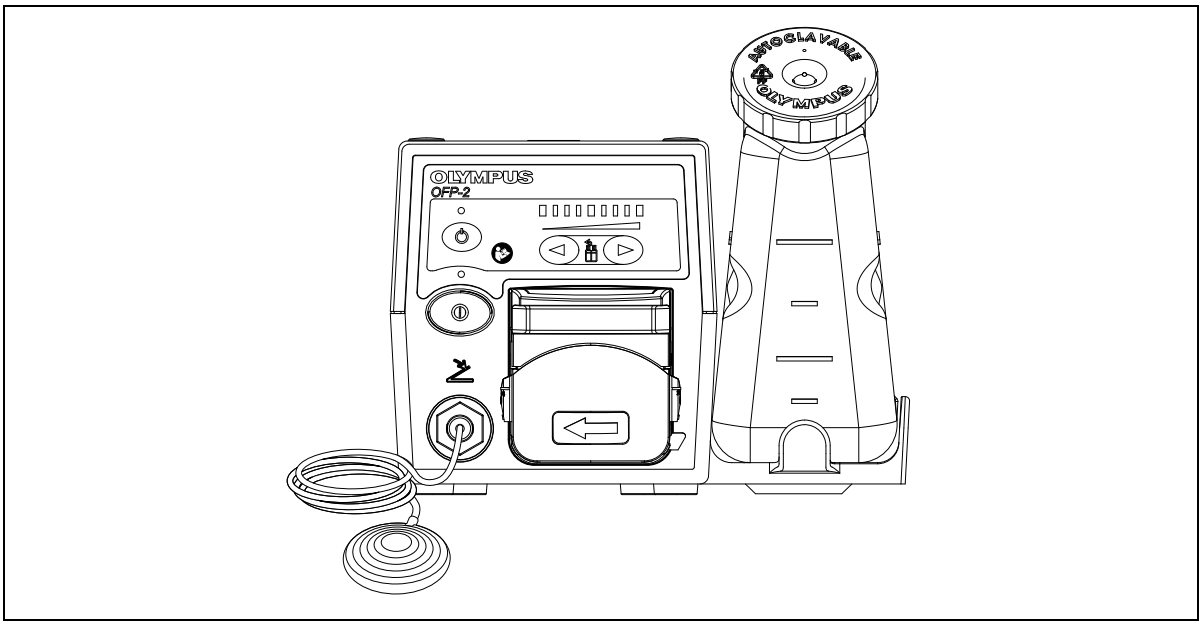


Figure 3.2

7. Route cabling neatly using the cable management provided on the workstation and connect the IEC mains power cable to the mains power inlet on the rear of the unit and an easily accessible, suitably grounded AC wall outlet or isolation/separation transformer socket. Ensure that access to the mains inlet is not obstructed

WARNING

Do not allow the power cable plug to become wet, otherwise this may cause electric shock.

NOTE

Refer to the workstation instructions for details on cable management and use of the isolation/separation transformer.

8. Referring to Figure 3.3, open the pump head lever on the pump head to access the pump rollers.

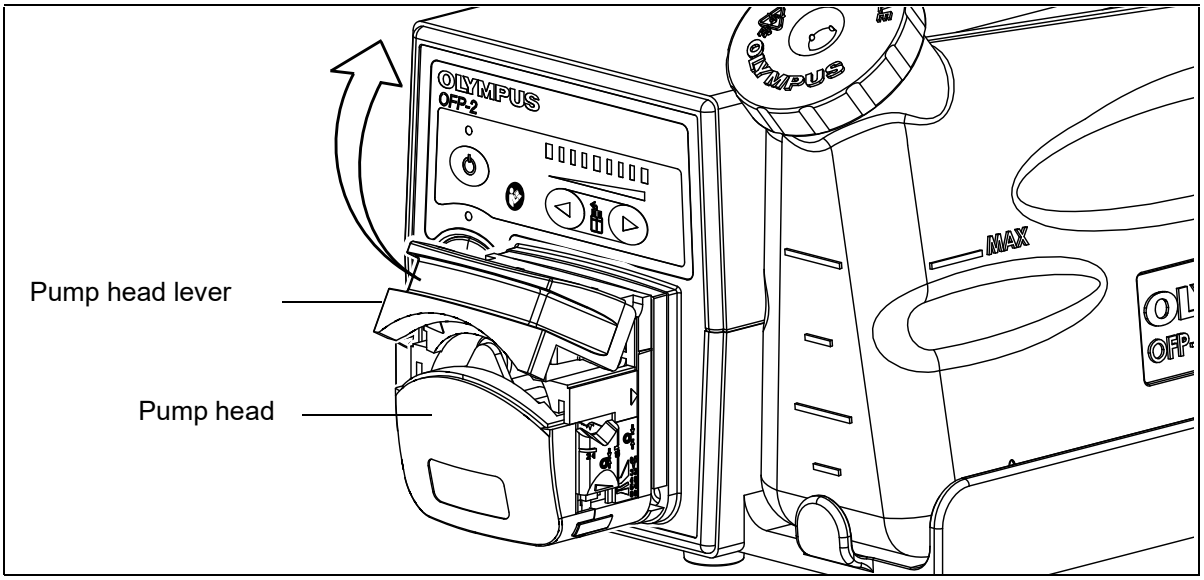


Figure 3.3

9. Confirm that the correct tube will be used for the procedure, noting the differences between the tube sets.

WARNING

The MAJ-1607 instrument channel water tube, MAJ-1681 Accessory Port Tube with Bottle Cap and MAJ-1682 Accessory Port Tube with Saline Spike are single-use disposable items. The MAJ-1608 and MAJ-1651 auxiliary channel water tube is a single day use item. Check the model name shown on the sterile package and the tube, and use them in accordance with their instruction manuals. Failure to do so may pose an infection risk and/or cause equipment malfunction. Ensure sterile tubing is free from damage. Do not use past the “use by“ date.

Model Name	Exchange frequency	Reason for exchange frequency
1. MAJ-1607 Instrument channel water tube (2.5m)	After each patient use	The inside of the tube may be contaminated when exchanging the endoscope, it should be changed after each patient use. Disinfection and sterilization are not available.
2. MAJ-1608 Auxiliary channel water tube (0.75m)	After one day use	If the tube is not replaced after one day use, it may cause contamination. Disinfection and sterilization are not available.

3. MAJ-1651 Auxiliary channel water tube (1.87m)	After one day use	If the tube is not replaced after one day use, it may cause contamination. Disinfection and sterilization are not available.
4. MAJ-1681 Accessory Port Tube with Bottle Cap (2.48m)	After each patient use	The tube and valve will become contaminated as it is connected directly to an EndoTherapy device. Disinfection and sterilization are not available.
5. MAJ-1682 Accessory Port Tube with Saline Spike (3.54m)	After each patient use	The tube and valve will become contaminated as it is connected directly to an EndoTherapy device. Disinfection and sterilization are not available.

10. For water container use, refer to Figure 3.4 and push the open end of the tube into the water container up to the indicator line noting the orientation of the tube as shown.

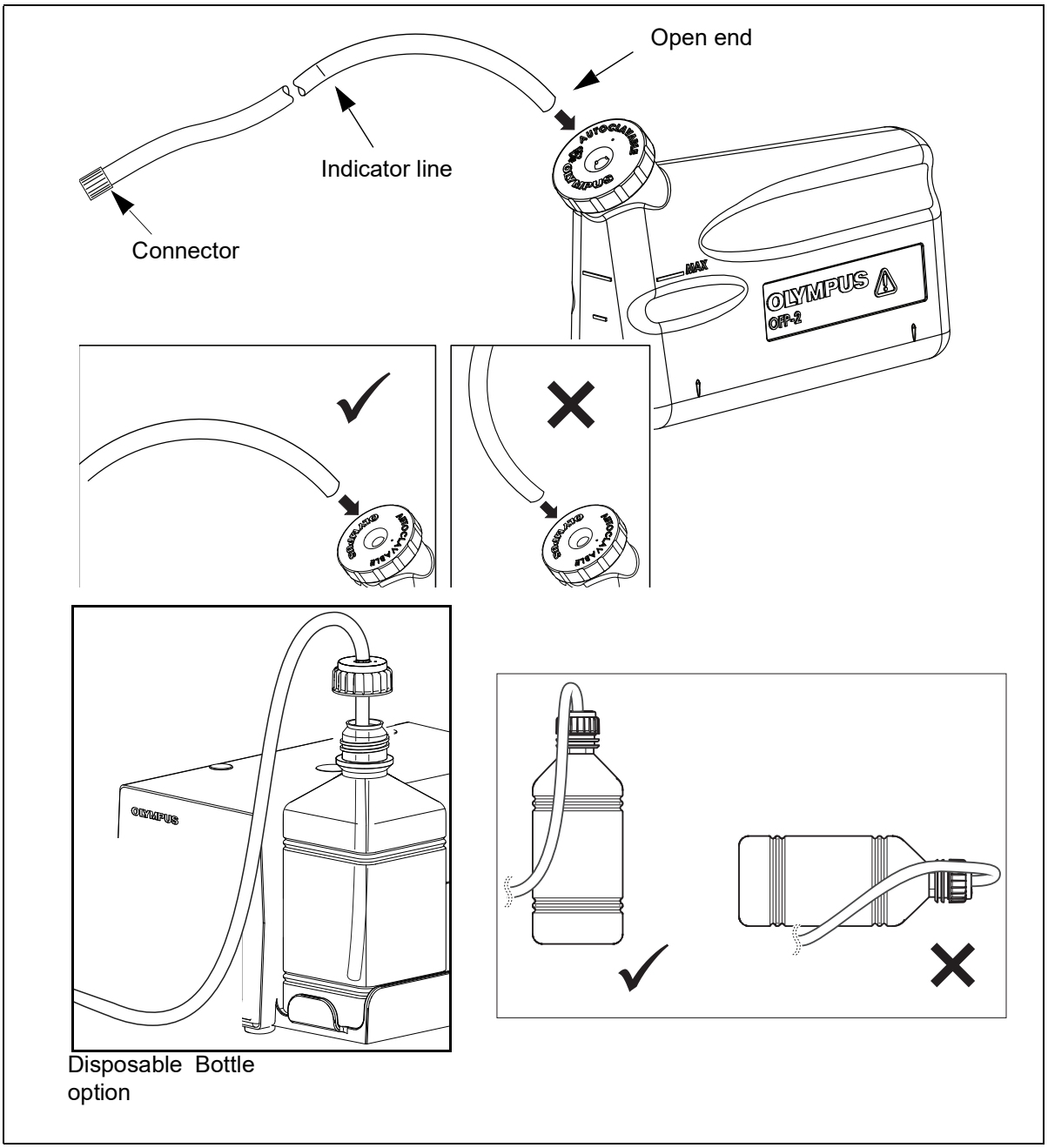


Figure 3.4

11. Position the water bottle upright in the irrigation pump bottle holder. Make sure that the fluid water level remains below the bottle cap.

NOTE

If the water bottle falls during use, cease insufflation and lens-flushing actions until the bottle has been reset to its correct position and resume insufflation once any water has purged from Air/Water valve.

12. For saline fluid bag use, refer to Figure 3.5. Remove the cap from the spike of the MAJ-1682 Accessory Port Tube and fully insert the spike with a twist into the correct port of the saline bag. Hang the saline bag on an IV pole.

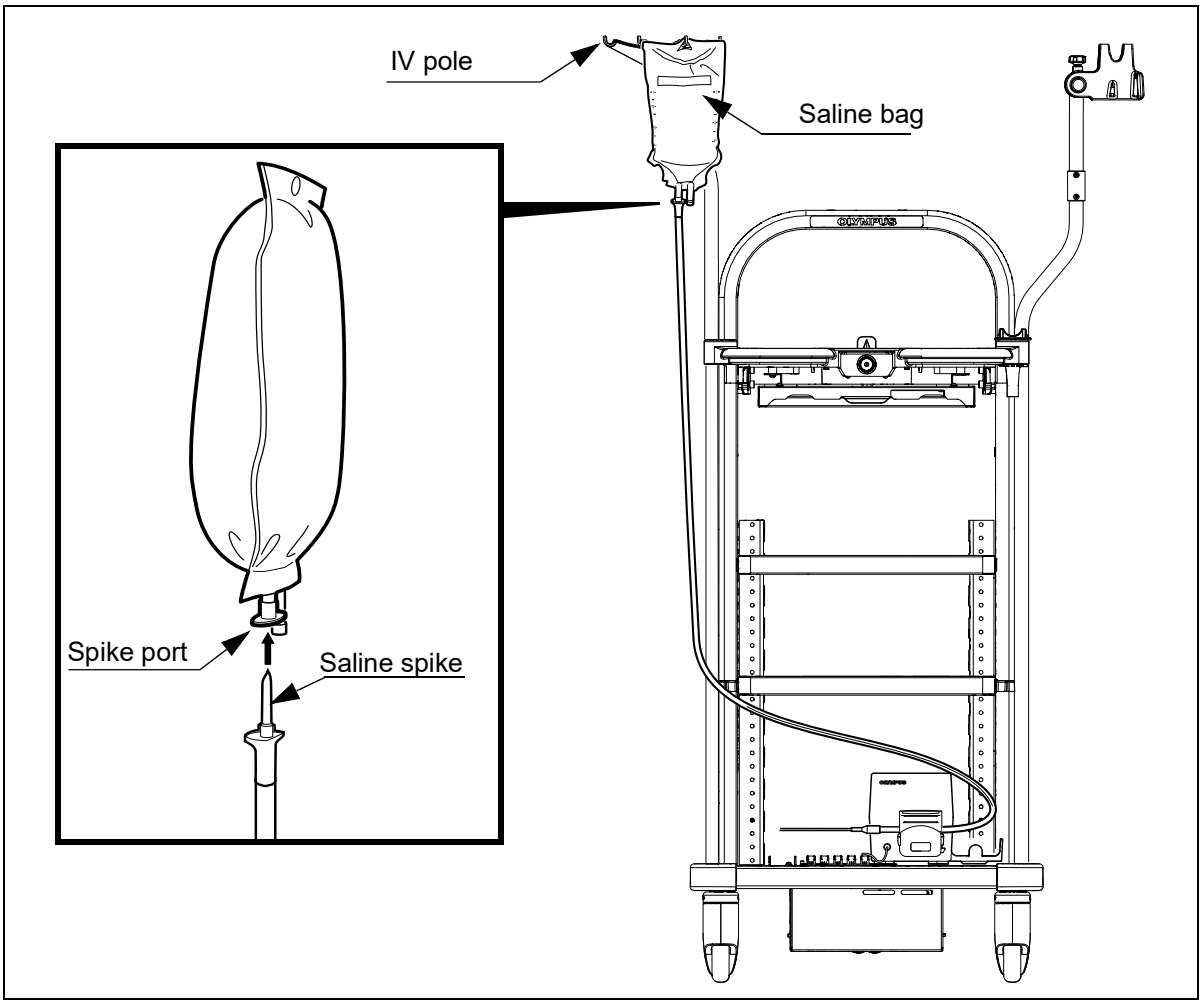


Figure 3.5

13. Manually rotate the roller in the pump head to align it centrally as shown in Figure 3.6

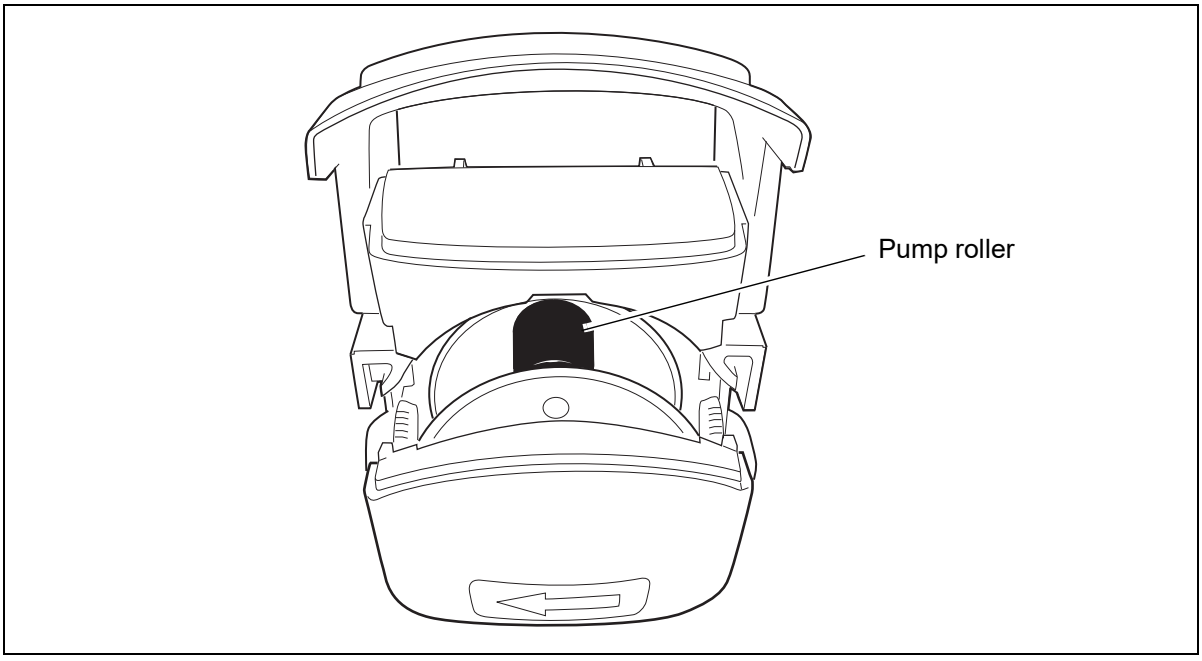


Figure 3.6

14. Insert the tube into the pump head as follows.

    (i) Ensure that the flow direction indicated by the arrows on the tube exactly correspond to the arrow on the pump head.

    (ii) Hold the tube on either side of the two remaining indicator lines and form a loop. Insert the formed loop fully into the pump head, taking care not to stretch the tube (Figure 3.7a).

    (iii) Release hold of the inserted tube and allow it to relax to a natural position within the pump head (Figure 3.7b).

    (iv) Close the pump head lever, ensuring that the tube is fully retained within the tube grips on the side of the pump head (Figure 3.7c). The tube should form a smooth radius when fitted (Figure 3.7)

CAUTION

- Be careful not to trap fingers when closing the pump head.

NOTE

- The tube must not be stretched when closing the pump head lever as this may affect the ability of the system to prime, and may also reduce flow rate.
- The tube must not be pinched with the side of the pump head when closing the pump head lever as this may affect the ability of the system to prime, and may also reduce flow rate due to reduced inner diameter of tube.
- If the system fails to prime within 10 seconds, optimum flow rate may not be achieved. In this instance it is advised that the tubing be reloaded into the pump head.

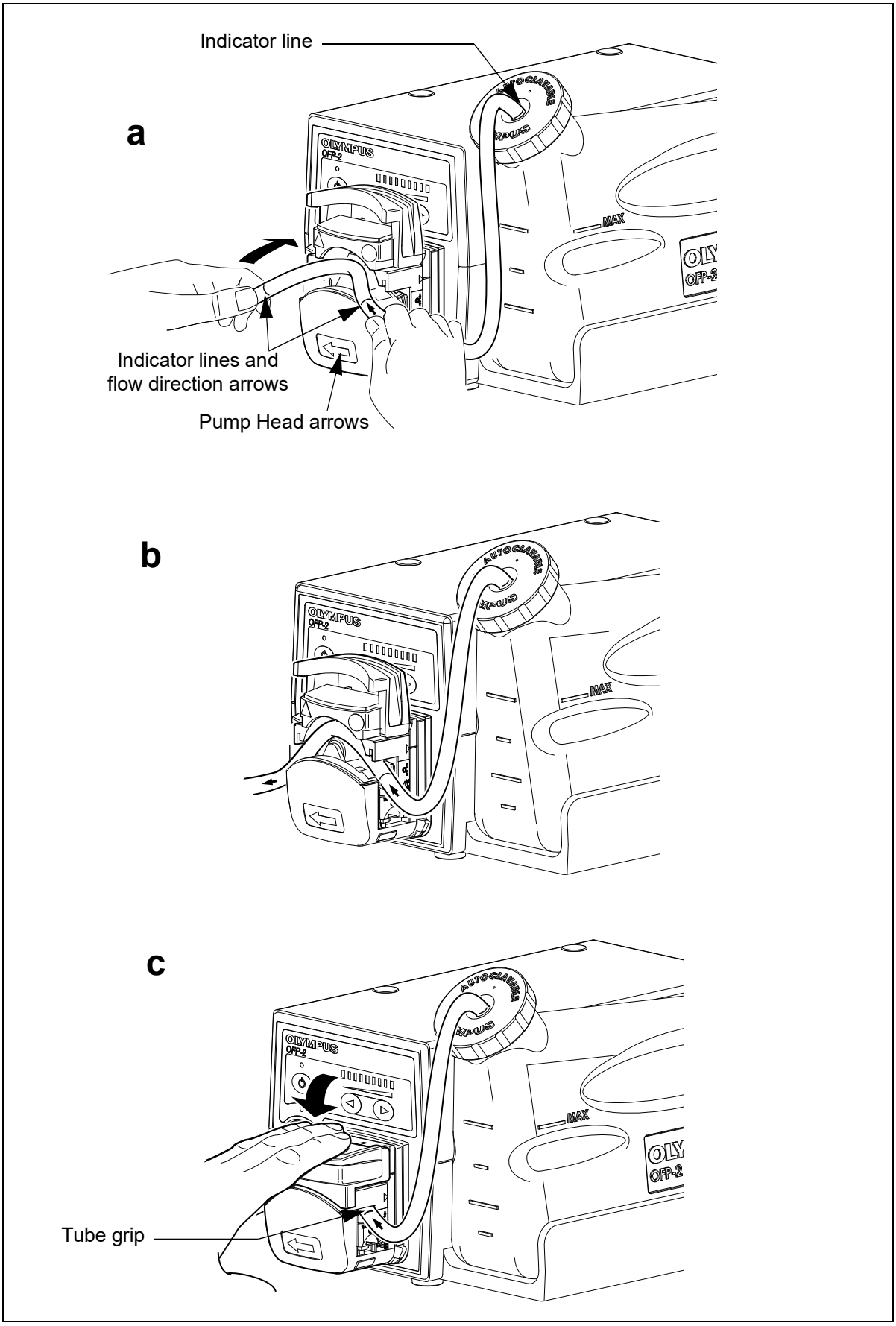

Indicator line
a
Indicator lines and
flow direction arrows
Pump Head arrows
b
c
Tube grip
OLYMPUS
OFP-2
MAX

Figure 3.7

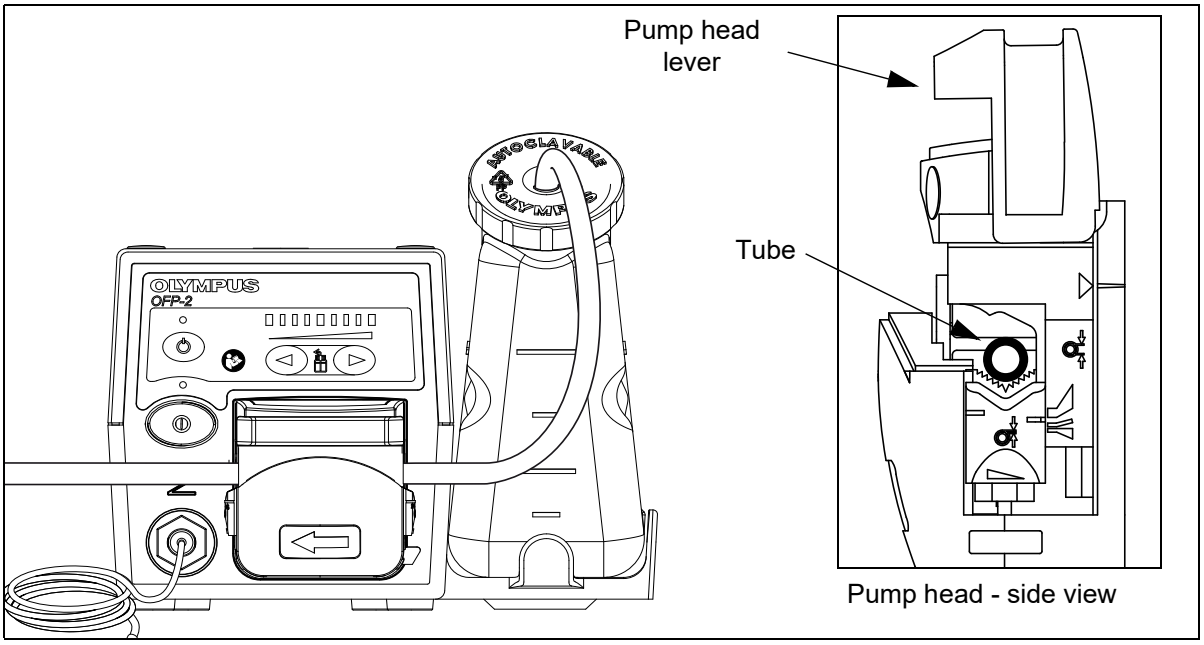


Figure 3.8

15. **Instrument channel connection (MAJ-1606/7)**: Refer to Figure 3.9 and connect the Luer lock connector on the MAJ-1607 water tube to the MAJ-1606 instrument channel adaptor attached to the instrument channel port on the endoscope.

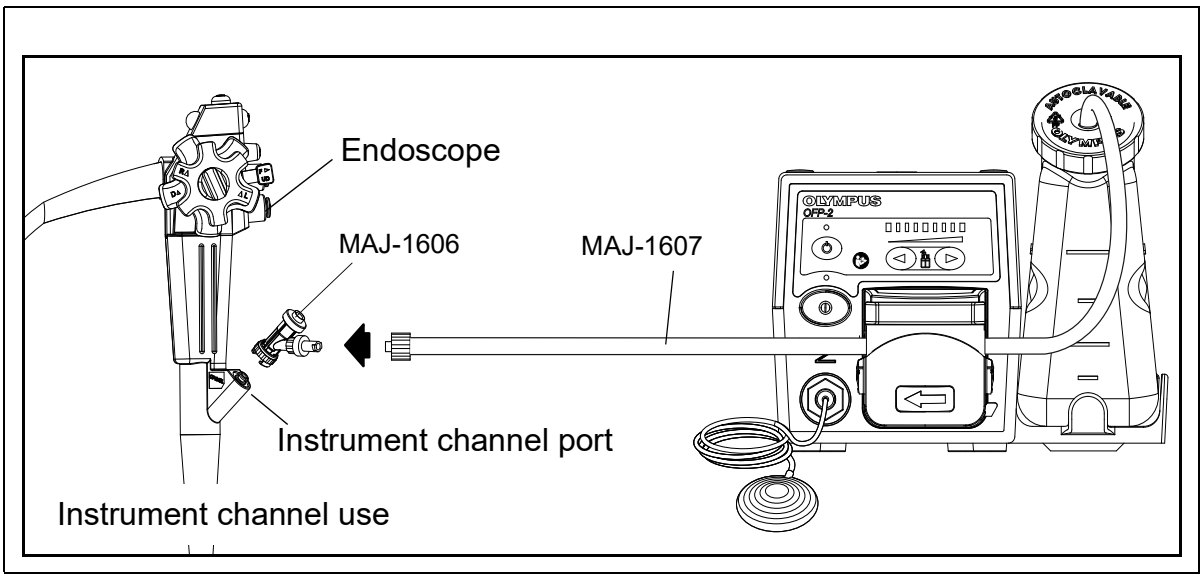


Figure 3.9

16. **Auxiliary channel connection (with MAJ-1608/MAJ-855)**: Refer to Figure 3.10 and connect the Luer lock connector on the MAJ-1608 water tube to the MAJ-855 auxiliary water tube attached to the auxiliary channel port on the endoscope.

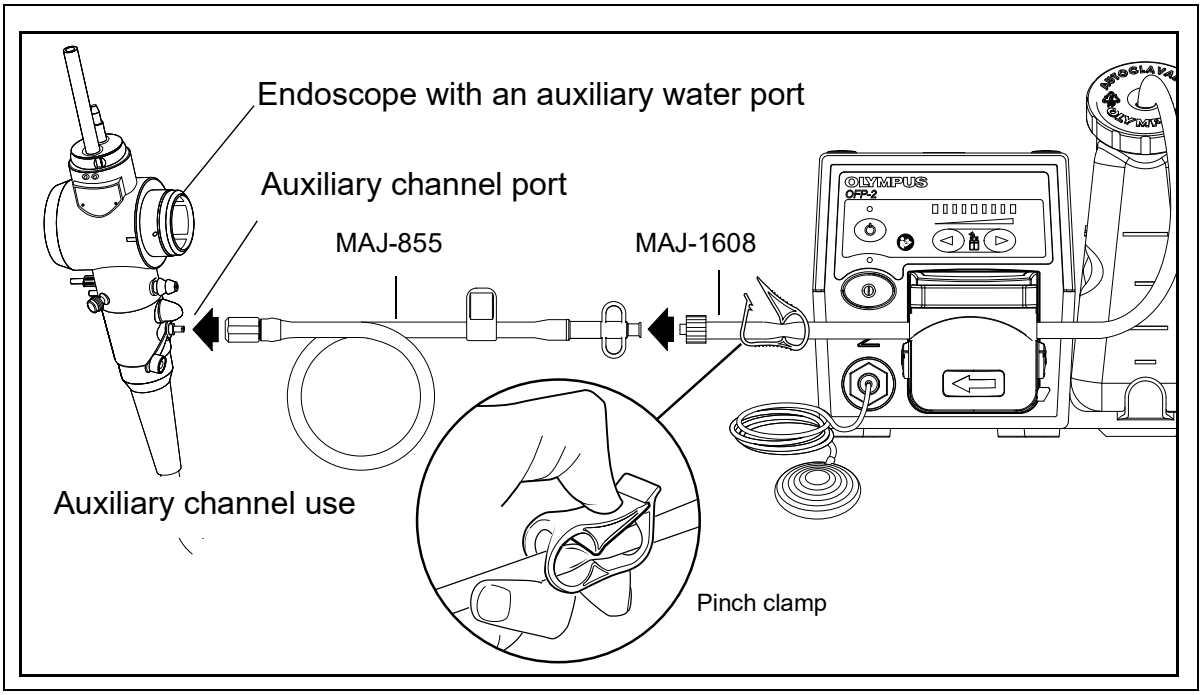


Figure 3.10

17. **Auxiliary channel connection (with MAJ-1651/2)**: Refer to Figure 3.11 and connect the Luer lock connector on the MAJ-1651 water tube to the MAJ-1652 auxiliary channel adaptor attached to the auxiliary channel port on the endoscope.

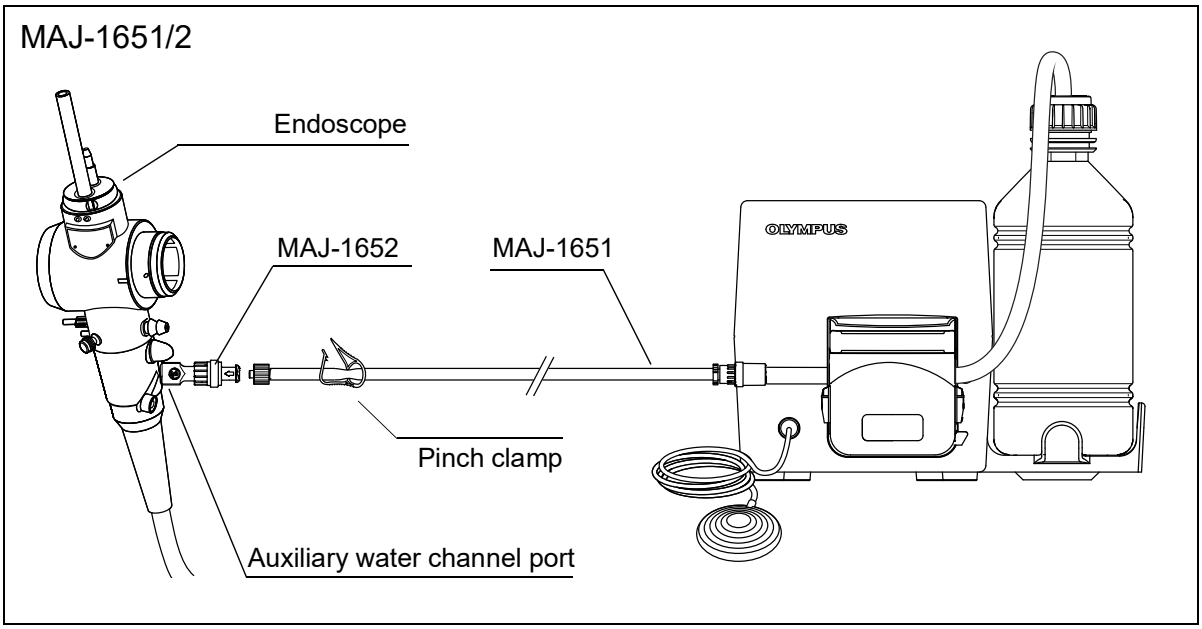


Figure 3.11

18. **EndoTherapy accessory connection (with MAJ-1681 and MAJ-1682)**:

    (i) Press the power switch on the OFP-2 front panel. The flow rate indicators sequence up and down during startup and the standby switch and lowest setting flow rate indicator illuminates green to indicate the unit is in “ON”.

    (ii) Press the ▶ flow rate control to maximize the water flow.

    (iii) Press and hold down the footswitch to activate the Peristaltic Pump. Continue to run the

OFP-2 until all air bubbles have been expelled from the tubing.

NOTE

- In cold conditions, it may be necessary to prime the tubing at lower pump speed.
- Priming is recommended between speed 5-9, depending on conditions.
- The MAJ-1681 and MAJ-1682 tubing must be primed with sterile saline in order to fully expel the air already in the tubing. During this, the tubing check valve may “whistle” until the air has been expelled. This is correct operation and not a malfunction.

(iv) Refer to Figure 3.12, connect the Luer lock connector on the MAJ-1681 tubing to the EndoTherapy device.

Set the pump speed to minimum.

WARNING

Use only in conjunction with compatible EndoTherapy devices listed in the MAJ-1681/MAJ-1682 instruction manual.

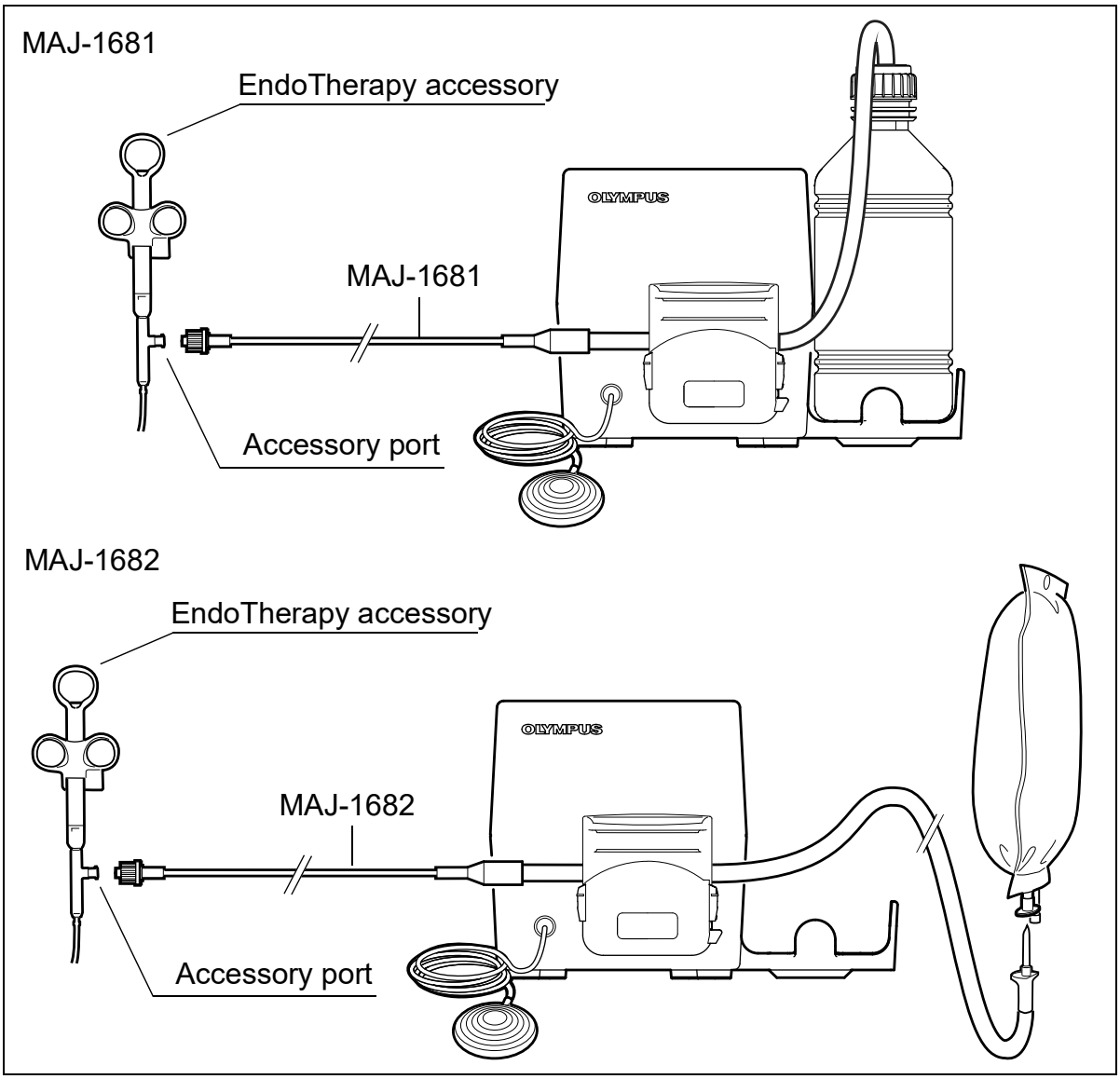


Figure 3.12

19. If using the optional MAJ-920 remote control cable, connect to the remote connector on the rear of the OFP-2 and the video system center. Refer to MAJ-920 instructions for setting endoscope remote switch functions and operating instructions.
20. Taking care not to damage any cables, replace the rear panel on the workstation.

Chapter 4 Operating instructions

WARNING

- To prevent inadvertent operation of the pump while fitting/changing the tube, the pump head lever is fitted with a cutout which prevents the pump head from operating when the pump head lever is opened.
- Each day before use, confirm that the pump head cutout is correctly working by visually checking that the pump rollers stop when the pump head lever is opened. If the cutout is found to be faulty, stop using the OFP-2 and contact Olympus.
- Before inserting the endoscope into the patient's body, prime the fluid path and check irrigation tubing and adapter for signs of leakage. If fluid leaks from the irrigation tubing and/or adapter, check tightness of connections. If fluid is found to still leak from the irrigation tubing and/or adapter, replace the affected item before continuing with the procedure.
- MAJ-1681 and MAJ-1682 tube sets must be primed without the EndoTherapy accessory attached so air can be removed. Flush the pump at speed setting 5-9 until all air pockets are gone, then attach the EndoTherapy accessory.

1. Press the power switch on the OFP-2 front panel. The flow rate indicators sequence up and down during startup and the standby switch and lowest setting flow rate indicator illuminates green to indicate the unit is in “ON”.

WARNING

Check correct illumination of all indicators during the startup sequence. If an indicator fails to illuminate, then stop using the OFP-2 and contact your nearest Olympus service centre.

NOTE

- Pressing the standby switch at this stage will change the standby switch indicator to amber, indicating that the unit is in “standby mode”. Pressing the standby switch again will change the standby switch indicator back to green, indicating that the unit is “run mode”. Any previously selected flow rate will be stored in memory, even when in “standby mode”, until the unit is switched OFF.
- Before opening the pump head lever for tube replacement/adjustment, press the standby switch to put the unit into “standby mode”. On subsequent closure of the pump head lever, press the standby switch again to switch the unit back into “run mode”.

2. Press the ▶ flow rate control to maximize the water flow. Press and hold down the footswitch until water exits from the endoscope or EndoTherapy device. Then release the footswitch to stop the water flow.

NOTE

- The tubes and the endoscope's auxiliary channel, instrument channel or EndoTherapy accessory, must be full of water for it to exit from the device. Continue to hold down the footswitch while this is happening.
- You can reduce the time it takes for water to start exiting from the endoscope or EndoTherapy device by pressing the footswitch while pushing down the pump head lever with your finger.
- Take care not to spray water over equipment, patient or operator when operating the OFP-2 with the endoscope or EndoTherapy device outside the patient.
- It may be found that the pump head moves from side to side during operation. This is perfectly normal and is indicative of the pump head attachment method.
- The MAJ-1681 and MAJ-1682 tube sets must be primed with sterile saline in order to fully expel the air already in the tubing. During this time, the tubing check valve may “whistle” until the air has been expelled. This is correct operation and not a malfunction.

3. Press the ◀ flow rate control to minimize the flow rate.

WARNING

For safety reasons, start the water flow at the minimum level and increase it progressively until the appropriate level for the patient's condition has been identified.

4. During the endoscopic procedure, adjust the flow rate using the ◀ and ▶ flow rate controls on the front panel. When flushing with an instrument channel, use air suction to remove water from the instrument channel.
5. Insert the endoscope into the patient after you have completed the necessary preparations in accordance with the endoscope manual.
6. While using the OFP-2 on a patient, adjust the flow rate using the ◀ and ▶ flow rate controls on the front panel.

WARNING

- The operator must assess the condition of the patient and use clinical and professional judgement to set the flow rate from the pump to a suitable level to avoid patient trauma. Vigorous flushing may cause bleeding from lesions or blood vessels.
- The flow control should always be set to minimum at the start of a procedure and be increased progressively to a level commensurate with the clinical condition of the patient.
- When flushing with ø2.0 to ø2.2mm instrument channel videoscopes, remove the EndoTherapy instrument from the MAJ-1606. Otherwise, leakage or spraying of potentially contaminated fluid may occur. With an EndoTherapy instrument inserted in the instrument channel, do not flush and extract at the same time, as there is a potential risk of spraying.

WARNING

- If high flow rates are required while accessory tools are inserted in the instrument channel, there is an increased risk of fluid leakage. Therefore, the user should slow the pump speed to reduce any fluid loss, or take precautionary measures to ensuring there is no danger to users, patients or equipment.
- If there is no fluid flow during use, switch off the OFP-2 and depressurise the system by disconnecting the tube from the MAJ-855 auxiliary tube, MAJ-1606 instrument channel adapter or EndoTherapy device. Otherwise, leakage or spraying of potentially contaminated fluid may occur, particularly in the event of endoscope or EndoTherapy device blockage.
- Clinical judgement should be used when filling the intra-abdominal area, as it is possible to raise the intra-abdominal pressure to a potentially unsafe level.
- Note that this unit can deliver flow rates through the instrument channel of the endoscope in excess of that which can be delivered when using a 50ml syringe.
- Before the procedure begins, ensure the water container has been filled with sterile fluid and the fluid path is primed.
- For EndoTherapy use, ensure that the supply of saline does not run out during operation of the OFP-2, as harm may be caused to the patient if air is injected into the submucosal layer.

CAUTION

- When inserting an EndoTherapy instrument or ultrasound probe in the MAJ-1606 instrument channel adapter, hold the instrument or probe as close as possible to the distal end and insert it straight it into the MAJ-1606 instrument opening.
- Prior to each use, ensure the tube connections are secure, watertight and routed to eliminate potential flow restrictions caused by, but not limited to, tube kinking or accidental tube compression. Keep the tubing clear of the patient at all times. In the event of entanglement, stop the procedure and re-route the tubing
- Activation of the pump while the tubing/EndoTherapy accessory is connected to the OFP-2 but not inserted into an endoscope may result in potentially contaminated fluid being pumped from the end of the system and coming into contact with the floor, electrical equipment and people in the area

NOTE

- When the footswitch is pressed continuously, the pump will operate continuously to a maximum of 20 seconds. Upon footswitch release, the pump will stop.

NOTE

- It may be found that the pump head moves from side to side during operation. This is perfectly normal and is indicative of the pump head attachment method.
- After the pump has stopped, the pump may rotate for approximately two seconds in the reverse direction. After each flush, it may appear that bubbles in the tube are flowing back to the water container from the OFP-2 pump head. This is a perfectly normal operation to help reduce the pressure within the tube.

7. To refill the water container while using it on a patient, press the standby switch to put the OFP-2 on standby, keep the pump head lever closed so the tube is not disturbed.
Pull the tube from the water container cap and remove the container from the unit. Unscrew the cap, fill the container with the appropriate fluid then secure the cap. Place the container back on the unit. Push the tube into the container cap up to the indicator line. Press the standby switch to put the OFP-2 back into “run mode”.

CAUTION

- During the water container refilling procedure, ensure that the tube is handled appropriately to prevent contamination.
- Should the tube become contaminated during the water container filling procedure, replace with a new tube.

8. After using it on a patient, remove the endoscope from the patient. If using this product to clean the endoscope's auxiliary channel, please do so in accordance with the endoscope instruction manual.
9. If intending to use auxiliary channel flushing on the next patient, remove the MAJ-855 auxiliary tube or MAJ-1652 adaptor from the pump tube. On connection of the new endoscope, new MAJ-855 auxiliary tube or MAJ-1652 adaptor must be connected to the pump tube to the MAJ-1608 auxiliary channel tube, fill the auxiliary channel with water by flushing from the endoscope.
10. Remove the MAJ-1608/MAJ-1652 auxiliary channel tube as follows:
    (i) Remove the tube from the water container and drain the auxiliary channel tube by pressing the footswitch to supply air.

WARNING

- The expelled liquid contains infectious material. Handle it appropriately.
- Do not supply air to the endoscope while it is inserted in the patient.

    (ii) Press the power switch to turn off the power supply.
    (iii) Disconnect the pump tube from the one-way valve (MAJ-855 or MAJ-1652).
    (iv) Open the pump head lever, remove the tube from the pump head and dispose of it in an appropriate manner.
    (v) Isolate the pump from the mains electricity at the end of use.
    (vi) Disconnection from mains supply is achieved by removal of mains lead from wall or transformer outlet sockets.
11. Remove the MAJ-1606 instrument channel adaptor and the MAJ-1607 instrument channel tube as follows:

(i) Remove the MAJ-1606 instrument channel adaptor from the endoscope.

(ii) Remove the MAJ-1607 instrument channel tube from the water container. Drain the MAJ-1607 instrument channel tube by pressing the footswitch to supply air.

WARNING

The expelled liquid contains infectious material. Handle it appropriately.

(iii) Press the standby switch to "standby mode". If finishing for the day, press the power switch to turn off the power supply.

(iv) Open the pump head lever and remove the MAJ-1607 instrument channel tube from the pump head.

(v) Discard the MAJ-1606 instrument channel adaptor and the MAJ-1607 instrument channel tube in an appropriate manner.

12. Remove the MAJ-1681 or MAJ-1682 accessory port tube as follows:

(i) Disconnect the tubing from the EndoTherapy device.

(ii) Remove the tubing from the water container or disconnect spike from the saline bag. Drain the tubing by pressing the footswitch to supply air.

WARNING

The expelled liquid contains infectious material. Handle it appropriately.

(iii) Press the standby switch to "standby mode". If finishing for the day, press the power switch to turn off the power supply.

(iv) Open the pump head lever and remove the tube from the pump head.

(v) Discard the tubing in an appropriate manner.

13. If used, the water container and cap should be removed from the OFP-2 and cleaned and sterilized prior to reuse.

Chapter 5 Cleaning and Sterilizing

WARNING

Water containers and caps are not cleaned or sterilized before shipment. Before using water container and caps for the first time, reprocess according to the instructions given in this Chapter.

5.1 Importance of cleaning, disinfection, and sterilization

The medical literature reports incidents of cross contamination resulting from improper cleaning, disinfection, or sterilization. It is strongly recommended that all individuals engaged in reprocessing closely observe all instructions given in this manual and the manuals of all ancillary equipment, and have a thorough understanding of the following items:

- Professional health and safety criteria of your hospital
- Individual cleaning, disinfection, and sterilization protocols
- Structure and handling of endoscopic equipment
- Handling of pertinent chemicals

For the types and conditions of the means of cleaning, disinfection, and sterilization to be adopted, please make judgments from your professional viewpoints.

WARNING

- Water containers and caps should be emptied, cleaned and sterilized at least once per day. Failure to do so could pose an infection control risk.
- Failure to properly clean and sterilize the water container and caps could lead to infection.
- During cleaning and sterilizing, wear appropriate personal protective equipment, such as eye wear, face mask, moisture-resistant clothing and chemical-resistant gloves that fit properly and are long enough so that your skin is not exposed.
- Patient debris and reprocessing chemicals are hazardous. Wear personal protective equipment to guard against dangerous chemicals and potentially infectious material. During cleaning and disinfection or sterilization, wear appropriate personal protective equipment, such as eye wear, face mask, moisture-resistant clothing, and chemical-resistant gloves that fit properly and are long enough so that your skin is not exposed. Always remove contaminated personal protective equipment before leaving the reprocessing area.
- The disinfection/sterilization room must be adequately ventilated. Adequate ventilation protects against the buildup of toxic chemical fumes.
- Turn off the OFP-2 and disconnect the power cord prior to cleaning and servicing.

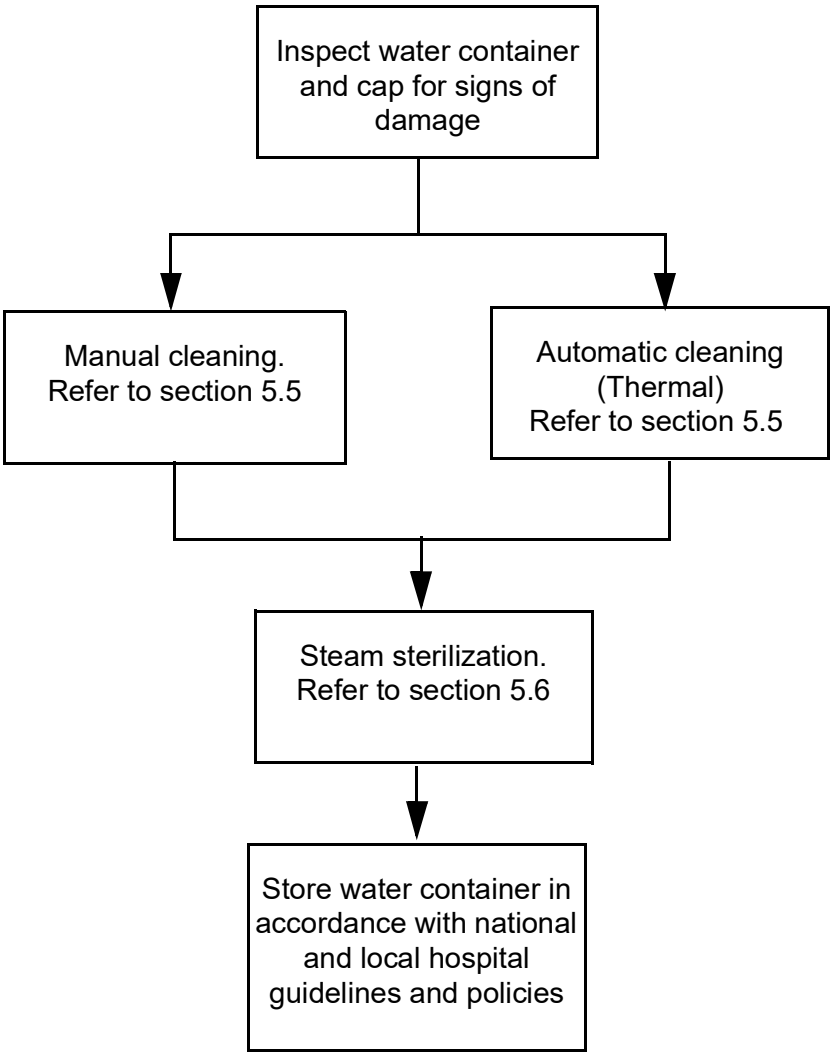
CAUTION

- Do not drop the water container or subject it to impacts. The container could become damaged and unusable.

CAUTION

- Prior to cleaning and sterilizing, remove the cap from the water container.
- Water container and cap have a service life of 1.5 years or 144 reprocessing cycles, whichever occurs sooner. Discoloration can occur following reprocessing.

5.2 Cleaning and sterilizing summary chart



5.3 Compatible reprocessing methods and chemical agents

Compatibility summary

Olympus endoscopic equipment is compatible with several methods of reprocessing. Certain components and accessories, however, are not compatible with some methods, which can cause equipment damage.

For appropriate reprocessing methods, refer to the table below, the recommendations of your infection control committee and all national and local hospital guidelines and policies.

	Methods validated in terms of biological efficacy and material durability				
	Steam sterilization (autoclaving) 137°C for 3 minutes	Ethylene oxide gas sterilization	Automatic cleaning (thermal) 93°C for 1 minute	Detergent solution	Ultrasonic cleaning
Water container		■	■		■
Water container cap		■	■		■

■ Compatible □ Not Compatible

WARNING

- Do not reuse detergent solution. Otherwise, it may be difficult to reprocess efficiently, and may pose an infection control risk.
- Use only those detergents which feature validated processes in accordance with national and local regulations and/or guidelines. There is an infection risk when using insufficient detergents.
- Alcohol is not a sterilant or high-level disinfectant.

Required detergent solutions

Use a medical-grade, low-foaming, neutral pH detergent or enzymatic detergent and follow the manufacturer's dilution and temperature recommendations. Do not reuse detergent solutions.

WARNING

Excessive detergent foaming can prevent fluid from adequately contacting the interior of the water container.

5.4 Required cleaning and sterilizing equipment

To perform proper reprocessing, the equipment listed in the following table is required. For details on preparation and directions on how to use the equipment, refer to the respective

instruction manuals or contact the equipment manufacturer.

		Cleaning	Steam Sterilization (Autoclaving)
Protective equipment	Appropriate personal protective equipment may include: Eye wear, face mask, moisture-resistant clothing, and chemical-resistant gloves.	○	○
Basin for detergent solution	Use a basin with sufficient depth to allow complete immersion of the instrument.	○	
Detergent solution	Use a neutral pH, low foaming, medical grade detergent solution.	○	
Packages for steam sterilization	Use packages compatible with steam sterilization.		○
Lint-free cloths		○	
Sealing device for sterile packaging	Sealing the packages may require a device such as a heat sealer. Prepare an appropriate sealing device according to the packages to be used.		○
Steam sterilizer	Use a steam sterilizer that will operate at the conditions specified in Section “Steam Sterilization (Autoclaving)” on page 42.		○

- Clean water
- Sponge brush

5.5 Cleaning

CAUTION

- When cleaning with an automatic cleaner, use only a detergent solution according to the pr EN ISO 15883-1 and 2.
- For details on use of the detergent solution, refer to its instructions for use.

NOTE

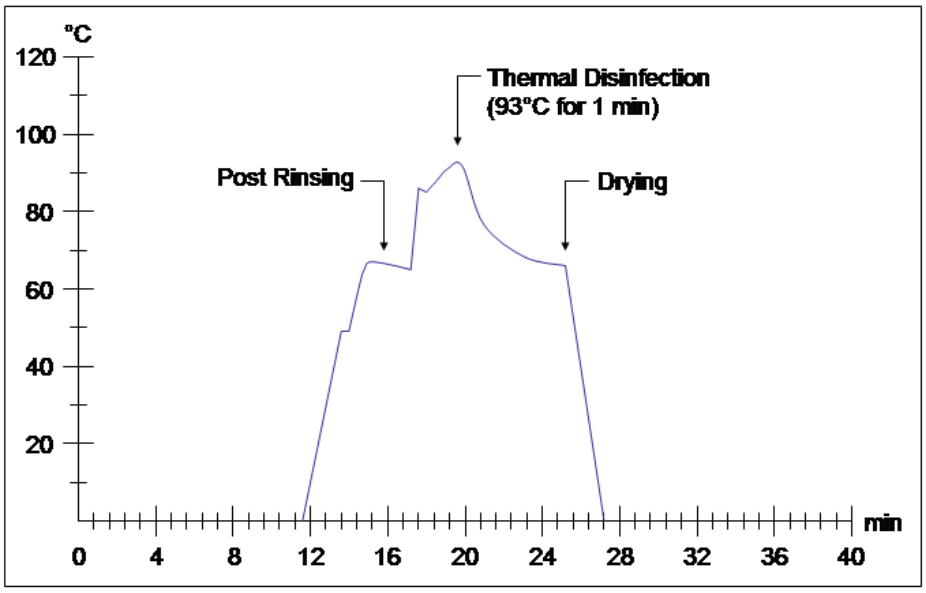
Olympus recommends the use of a washer/disinfector which has been designed to meet EN ISO 15883-1 and 2 and/or to HTM 2030.

1. Wear the protective equipment detailed in Section “Required cleaning and sterilizing equipment” on page 40.
2. Remove the cap from the water container.

3. Clean the water container and cap with a thermal washer ensuring that the water container(s) are loaded in such a way as to allow a direct jet of fluid into the container. Failure to do this may affect the cleaning efficacy of the container.

NOTE

The water container and cap have been tested for material compatibility in a thermal washer using the washing cycle profile detailed below.



4. When washing manually, clean the water container's interior, exterior and cap using detergent solution under the level of the water using a soft non-metallic scrub brush or a piece of clean gauze. Rinse thoroughly with tap water.
5. Dry thoroughly using clean, lint-free cloths.

5.6 Steam Sterilization (Autoclaving)

WARNING

- Remove the cap from the water container before sterilizing both of them.
- Before taking the water bottle and cap assembly package out of the autoclave, let it cool down to room temperature. Otherwise, it may cause burns.
- Inspect each equipment package for openings, tears, or other damage. If the equipment package is open or damaged, seal the water bottle or cap assembly in a new package and resterilize it as described below.
- Allow the packages to dry within the autoclave, using the autoclave's drying cycle (if available) or by opening the door of the autoclave and allowing the packages to air-dry. Handling a wet package can compromise its sterility.
- Always leave space between the packages in the autoclave. If packages are placed too close together, effective sterilization will not be possible.

WARNING

- The results of sterilization depend on various factors such as how the sterilized instrument was packed or the positioning, method of placing and loading of the instrument in the sterilization device. Please verify the sterilization effects by using biological or chemical indicators. Also follow the guidelines for sterilization issued by medical administrative authorities, public organizations or the infection management sections at each medical facility, as well as the instruction manual of the sterilization device.

CAUTION

Sudden changes in temperature may damage the instruments.

Follow the guidelines of the medical facility when steam sterilizing. Operate the steam sterilizer in accordance with the steam sterilizer instruction manual or with the maker instructions.

1. Before steam sterilizing, the water container and cap must be thoroughly cleaned and dried. Residual moisture inhibits sterilization.
2. Place the water container and cap in a separate package, then place the sealed packages in the steam sterilizer and steam sterilize them at the conditions given below.

   For details on operation of the steam sterilizer, refer to the instruction manual for the steam sterilizer or other manufacturer instructions.

Minimum Hold Temperature	Minimum Exposure Time	Guideline/Standard Reference
121 – 124°C	15 mins	EN 285: 2006, HTM 2010:1994
126 – 129°C	10 mins	EN 285: 2006, HTM 2010:1994
132°C	4 mins	ANSI/AAMI ST79:2006
134 – 137°C	3 mins	ANSI/AAMI ST79:2006 EN 285: 2006 HTM 2010:1994

CAUTION

Do not exceed a maximum autoclave temperature of 137°C (279°F), nor an exposure time greater than 20 minutes, otherwise damage to the equipment may result.

Chapter 6 Care and Storage

6.1 Care

WARNING

- After wiping with a piece of moistened gauze, dry the OFP-2 thoroughly before using it again. If it is used while still wet, there is the risk of an electric shock.
- When cleaning the OFP-2, always wear appropriate personal protection equipment. Blood, mucus and other potentially infectious material adhering to the OFP-2 could pose an infection control risk.

CAUTION

- Do not use harsh or abrasive cleaning materials on the OFP-2 as damage may result.
- Ensure all surfaces are thoroughly dried before reusing the OFP-2.
- Ensure footswitch is removed from the floor and stored safely to prevent it being damaged.
- The pump has a good, broad chemical resistance to inorganic acids, saline solutions, alkalis, some hydrocarbons and a large number of oils and greases. It is suitable for wipe down but not for long term contact with alcohols. The case may be damaged by contact with strong acids or strong solvents.
- Do not clean the remote control socket and/or the mains power inlet. Cleaning them can deform or corrode the contacts, causing damage to the OFP-2.
- Do not autoclave or gas sterilize the OFP-2. These methods will damage it.
- Do not wipe the external surface with hard or abrasive wiping material. The surface will be scratched.

NOTE

- There are no user serviceable parts inside the pump head.
- If the pump head requires replacement or thorough cleaning, detach and reattach the pump head using the guidelines given in Section “Pump Head Replacement” on page 46.

If the OFP-2 is soiled, perform the following cleaning procedure immediately after use. If cleaning is delayed, residual organic debris will begin to solidify, and it may be difficult to effectively clean the OFP-2. The OFP-2 should also be cleaned routinely.

1. Turn the OFP-2 OFF and disconnect the power cord.
2. Should the equipment become soiled with blood or other potentially infectious materials, first wipe off all gross debris using a neutral detergent, then wipe with a lint-free cloth moistened with a surface disinfectant.
3. Wipe the surface of the OFP-2 using a soft, lint-free cloth moistened with 70% ethyl or isopropyl alcohol to remove dust, dirt, etc.
4. Dry the OFP-2 with a clean, lint-free cloth.

6.2 Storage

WARNING

- Do not store the OFP-2 in a location exposed to direct sunlight, X-rays, radio activity or strong electromagnetic radiation (e.g. near microwave medical treatment equipment, short-wave medical treatment equipment, MRI equipment, radio or mobile phones). Damage to the OFP-2 may result.
- The OFP-2 should be stored within the environmental conditions given in “Specification” on page 51.

1. Turn the OFP-2 OFF and disconnect the power cord.
2. Disconnect all ancillary equipment connected to the OFP-2.
3. Discard the water tube and MAJ-1606 if used. Reprocess the water container and the cap prior to storage.
4. Store the equipment at room temperature in the horizontal position in a clean, dry and stable location.

Chapter 7 Maintenance and Repair

7.1 Routine Maintenance

The following routine maintenance should be performed at the intervals specified:

Hospital Engineer or Olympus - Annually:

- Check that the power cable is in good condition.
- Detach the pump head (Section “Pump Head Replacement” on page 46), and wipe the pump head thoroughly with a mild detergent solution. Check moving parts of the pump roller for freedom of movement.
- Check the unit externally for signs of damage.
- Perform electrical safety tests in accordance with EN IEC 62353:2008. It is recommended that testing includes:
  1. Protective earth resistance. Detach the pumphead as described above and test to the three torx head screws.

     It is not necessary to test the remote control connector on the rear panel as electrical separation from the mains part is ensured inside the unit.
  2. Leakage currents.
  3. Insulation resistance.
  4. Functional test.

7.2 Checking the Flow Rate

The pump head is a consumable. Its performance will deteriorate as the number of usages increases. The pump head may have deteriorated if the flow rate is low, if the strength of water flow seems weak or if it takes a long time for water to appear. If the contents of Chapter 10 "Troubleshooting" do not help you to solve the problem, measure the water flow as shown below. If the water rate is insufficient we recommend that you replace the pump head.

1. Insert the specified water tube (MAJ-1607 or MAJ-1608) to the pump head.
2. Set the flow rate to "9" and pump until water exits from the tube in order to purge the water tube of air.
3. Put the end of the tube in a container (beaker etc) with volume measurements on it, and pump for 20 seconds.
4. When the flow rate falls below 200ml (equivalent to 600ml/min), replace the pump head referring to Section “Pump Head Replacement” on page 46.

7.3 Pump Head Replacement

Replace the pump head as follows:

1. Detach the pump head

   Switch the power supply OFF and then rotate the pump head 45° anti-clockwise with one hand, while pressing and holding the pump head release lever with the other hand. Slowly take the pump head off the mounting plate (Figure 7.1).

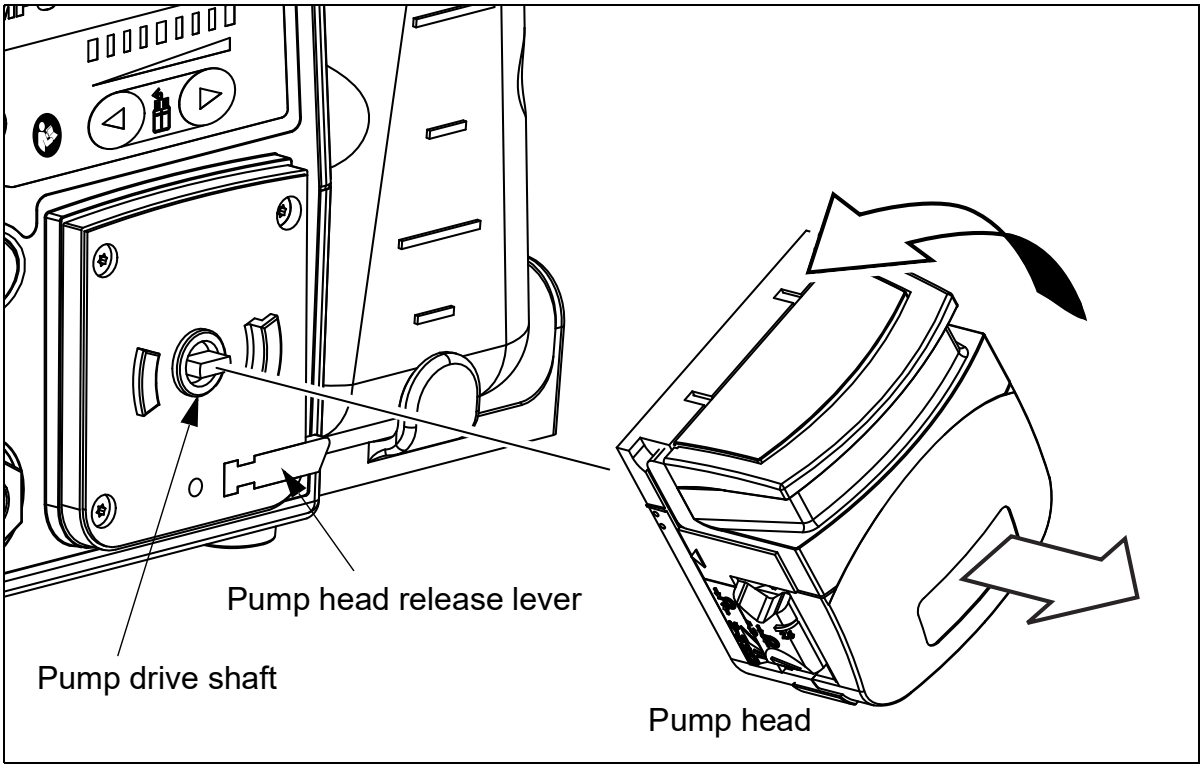


Figure 7.1

2. Attach the pump head

Tilt the pump head approximately 45° as shown in Figure 7.2, and attach it to the mounting plate. Align the pump drive shaft with the drive slot on the back of the pump head (Figure 7.3). Then rotate the pump head clockwise until it locks into an upright position.

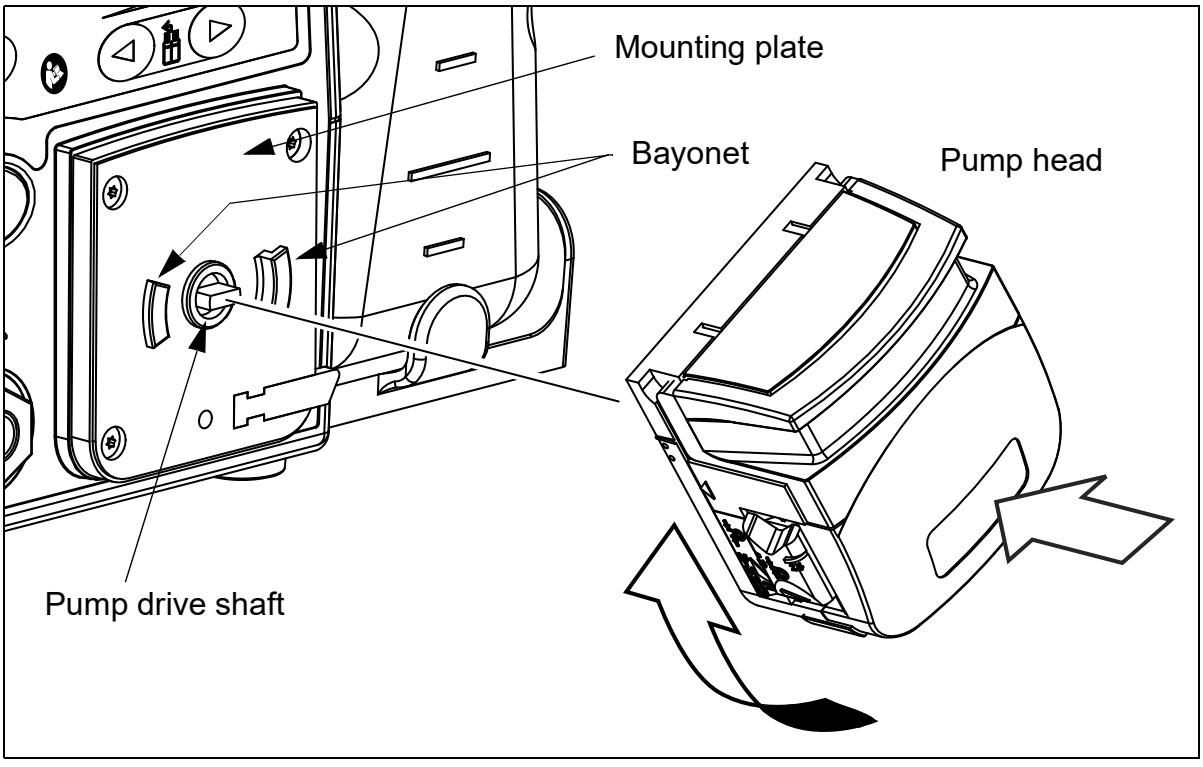


Figure 7.2

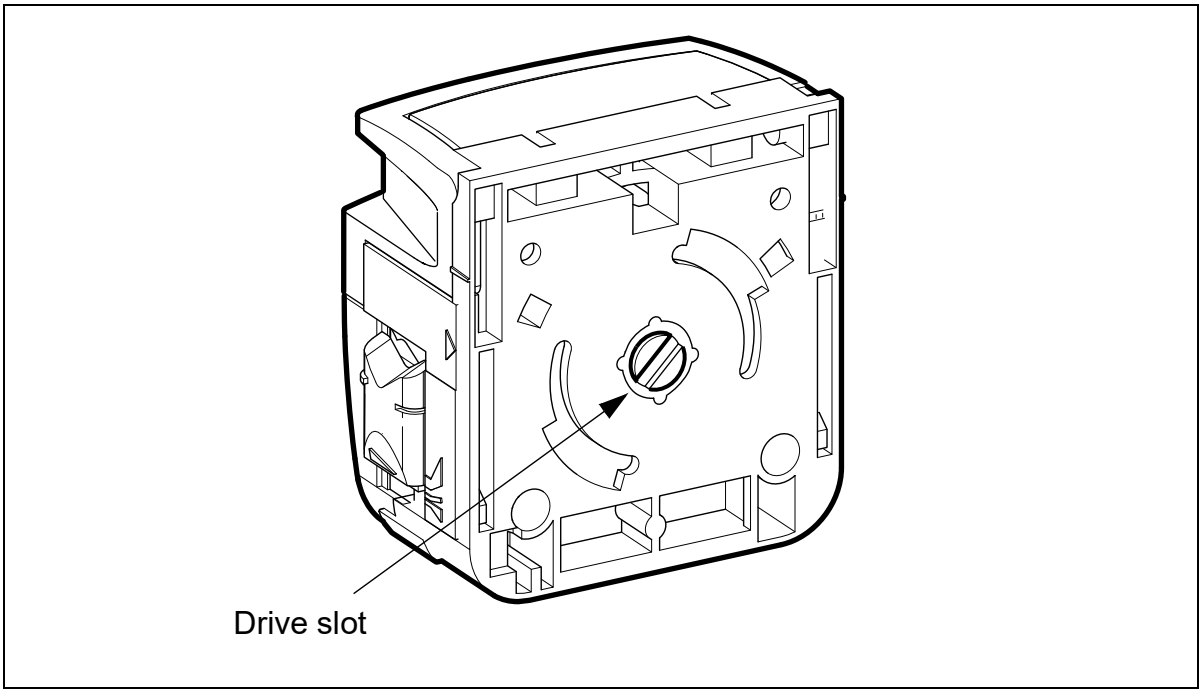


Figure 7.3

3. Turn the OFP-2 power supply ON and confirm that the control panel indicators illuminate and the standby LED then illuminates green.
4. Press the footswitch and confirm that the pump runs.
5. Lift the pump head lever and confirm that the standby LED turns to orange and the pump head does not rotate.
6. Confirm that the flow rate is sufficient following the guidelines in Section “Checking the Flow Rate” on page 46.

WARNING

If the events described in the above steps 3 to 6 are not observed, immediately switch the unit's supply OFF, disconnect the power cord and contact Olympus.

7.4 Fuse Replacement

WARNING

- The fuse must always be replaced with the fuse specified within “Care and Storage” on page 44. Failure to do so may cause malfunction or failure of the OFP-2, causing a fire or electric shock hazard.
- Turn the OFP-2 OFF and unplug the power cord from the back of the unit prior to removing the fuse drawer.

1. Turn the OFP-2 OFF and disconnect the power cord from the mains power inlet.
2. Referring to Figure 7.4, press the tab downwards to release the fuse drawer, pull out the drawer and replace both fuses.

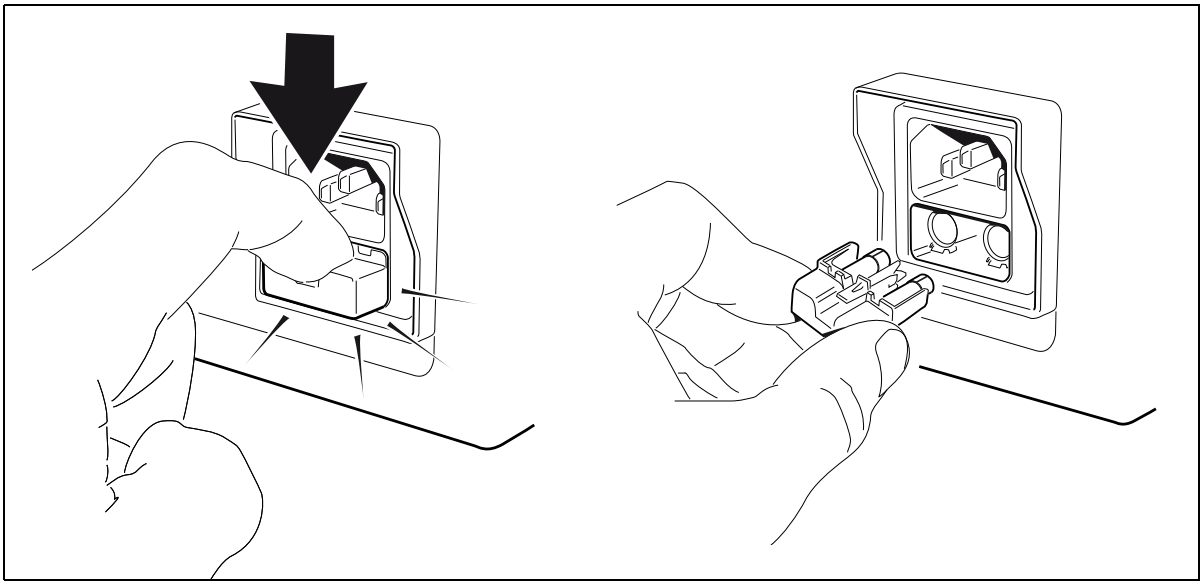


Figure 7.4

3. Hold the front of the unit with one hand to prevent it from moving, then insert the fuse drawer into the OFP-2 mains power inlet and push until it clicks into position.

CAUTION

Always ensure the fuse drawer is pushed fully home following maintenance/repair, as failure to do so may cause the mains power outlet to overheat.

4. Plug in the power cord and turn the OFP-2 ON, confirm the power output.

WARNING

If the power fails to come on after replacing the fuses, unplug the power immediately from the mains power inlet and contact Olympus.

CAUTION

If the fuses continue to blow, stop using the unit and contact Olympus or hospital engineer.

7.5 Repair

The OFP-2 must only be serviced/repaired by suitably qualified technical personnel. If repair is required, contact Olympus.

Olympus will not be responsible for damage or injury to equipment or personnel caused by unauthorised repair or modification to this unit.

If the pump fails to operate:

- Check the items detailed in “Troubleshooting” on page 54.
- Check the condition of both fuses located in the fuse drawer in the mains power inlet at the rear of the unit (see Section “Fuse Replacement” on page 48). Check the fuse in the power cable plug as appropriate.

Chapter 8 Spares

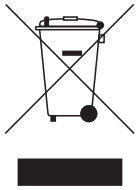
The Spares shown below are consumables. Please replace them in the event of their deterioration or failure.

NOTE

To maintain standards compliance, use only the following Spares with this product which are available from Olympus.

Item	P/no
Footswitch	7501357
Fuse T2.5AH 250V (pack of 5)	K10008954
Power cable (UK)	7145454
Power cable (USA)	7318766
Power cable (Japan)	K10037133
Power cable (Europe)	7145462
Power cable (RoW)	7318561
Water container cap	K10008300
Water container (2 litre)	K10008299
Pump head	K10011134

Chapter 9 Specification

Items	Specifications	
Product name	Olympus Flushing Pump OFP-2	
Classification (electromedical equipment)	Standards compliance	ETL CLASSIFIED c ETL us LISTED Intertek This symbol on the OFP-2 indicates it is listed and classified by Intertek Testing Services as meeting the requirements of AAMI ES60601-1, and is certified to CSA C22.2 No. 60601-1
	Electro–magnetic compatibility	This product complies with the requirements of EN IEC 60601-1-2:2014 Edition 4 for emissions and immunity, and as such, its operation is unlikely to be affected by, or cause interference with, equipment meeting appropriate EMC standards. As a precaution, equipment which may be sensitive to interference outside the limits specified by EN IEC 60601-1-2:2014 Edition 4 should not be placed in close proximity to the OFP-2.
	Type of protection against electrical shock	Classification according to: IEC 60601-1:2005 + A1:2012 Edition 3.1 EN 60601-1:2006 + A1:2013 ANSI/AAMI ES 60601-1:2005/(R)2012 - Class I
	Degree of protection against electrical shock	In accordance with IEC 60601-1:2005 + A1:2012 Edition 3.1, EN 60601-1:2006 + A1:2013 and UL 60601-1:2003, the OFP-2 provides an adequate degree of protection against electrical shock as if it has an applied part isolated from all other parts of the equipment. The endoscope is the applied part. The OFP-2 is an accessory to the applied part.
	Degree of protection against explosion	None: the Olympus OFP-2 must NOT be used in the zone of risk of flammable anaesthetic gases.
	Mode of operation	Continuous
Regulatory status	European Economic Area (EEA)	CE 2797 This mark on the product indicates compliance with Medical Device Regulation 2017/745, as amended relating to medical devices, Class IIa. The year of manufacture is given in the second and third digits of the serial number.
End of life		 In accordance with European Directive 2002/96/EC on Waste Electrical and Electronic Equipment, this symbol indicates that the product must not be disposed of as unsorted municipal waste, but should be collected separately. Refer to your local Olympus distributor for return and/or collection systems available in your country.
Year of manufacture		21501234 Displays the last two digits of the year of manufacture.  The year of manufacture is shown on the packaging label, combined with the ‘MANUFACTURER’ symbol.
Dimensions and weight	Dimensions	Height: 166 mm (220mm with water container) Width: 244 mm Depth: 385 mm
	Weight	4kg (with empty water container)

<table>
<tr><td>Power requirements</td><td colspan="3">Power supply
100–240V~

Frequency
50/60Hz

Fusing
2 x T2.5AH 250V

Power rating
100VA

Marking: The mark ~ on the product indicates the requirement for an AC power supply.</td></tr>
<tr><td rowspan="7">Power cables</td><td>K10001141</td><td>(USA & Canada)</td><td>NEMA 5-15P Hospital grade plug, 2.5m long,
IEC 320 appliance connector</td></tr>
<tr><td>K10001142</td><td>(Japan)</td><td>NEMA 5-15P Hospital grade plug, 2.5m long,
IEC 320 appliance connector</td></tr>
<tr><td>K10001143</td><td>(Europe)</td><td>Straight Schuko plug, 2.5m long,
IEC 320 appliance connector</td></tr>
<tr><td>K10001144</td><td>(UK)</td><td>13A plug to BS1363, fused 5A, 2m long,
IEC 320 appliance connector</td></tr>
<tr><td rowspan="2">K10001145</td><td>(ROW)</td><td>Flying leads (no power plug), 3m long,
IEC 320 appliance connector.
Other cord sets may be available from local supplier.</td></tr>
<tr><td colspan="2">Important
The cores of the power cable supplied with this instrument are coloured in accordance with the following code:
Brown — Hot wire (Live)
Blue — Neutral
Green/Yellow — Ground (Earth)</td></tr>
<tr><td rowspan="3">Environmental conditions</td><td>Ambient temperature</td><td>Operational:
Storage:</td><td>+10°C to +40°C (+50°F to +104°F)
-40°C to +70°C (-40°F to +158°F)</td></tr>
<tr><td>Relative humidity</td><td>Maximum:</td><td>95% at 40°C relative non–condensing</td></tr>
<tr><td>Atmospheric pressure</td><td>Operational:
Storage:</td><td>70–106 kPa
23.5–106 kPa</td></tr>
<tr><td>Fluid ingress</td><td colspan="3">To IPX0. No protection.</td></tr>
<tr><td>Resistance to chemicals</td><td colspan="3">The external surfaces of the Olympus OFP-2 are resistant to: 2% Aqueous Neutral Detergent, 70% Ethyl alcohol (J&J wipes), 70% Isopropyl Alcohol, Water, Anti-foaming agent, Saline</td></tr>
<tr><td>Pump type</td><td colspan="3">Peristaltic</td></tr>
</table>

Pump operation	**Water feed**: controlled by pneumatic footswitch or remotely from endoscope via compatible OLYMPUS video processor. **Maximum pressure:** Less than 1300 kPa **Flow rate:** variable, controlled from front panel. Flow rate delivery from the pump will depend on the length and type of OLYMPUS EVIS EXERA/EXERA II/LUCERA/EUS gastrointestinal/colono/ultrasound videoscope or EndoTherapy Accessory attached. The operator must therefore assess the condition of the patient and use clinical judgement to set the flow rate from the pump to avoid causing patient trauma.
	For endoscopes incorporating an auxiliary water channel and using auxiliary water channel tube MAJ-1608/MAJ-1651: The flow rate when using the CF-Q180AL should be approx. 230ml/min when the pump head is new and its flow setting is 9 (maximum). The flow rate will reduce as the pump head deteriorates. We recommend flow settings of 1 - 6 for auxiliary water channel use.
	For instrument channel flushing (1): The flow rate when using the CF-Q260AL/DL (3.2mm diameter channel) without an instrument inserted should be approx. 785ml/min when the pump head is new and its flow setting is 9 (maximum). The flow rate will reduce as the pump head deteriorates. We recommend flow settings of 5 - 9 for instrument channel use.
	For instrument channel flushing (2): The flow rate when using the GIF-Q260 (2.8mm diameter channel) with a 2.5mm diameter ultrasound probe inserted should be approx. 100ml/min when the pump head is new and its flow setting is 9 (maximum). The flow rate will reduce as the pump head deteriorates. We recommend flow settings of 5 - 9 for instrument channel use.
	For EndoTherapy device flushing : The flow rate when using the single-use electrosurgical knife KD-655U should be approx 45ml/min when the pump head is new and its flow setting is 5. The flow rate will reduce as the pump head deteriorates. We recommend flow settings of 1-5 for EndoTherapy device use.
	If the pump is connected to any other endoscope or device other than those specified in these instructions, then damage to the pump or attached device, or injury to the patient or user may result.
Water container	The water container supplied with the unit has a 2 litre capacity and will withstand a minimum of 144 steam sterilisation cycles up to 137°C for 3 minutes duration.

Chapter 10 Troubleshooting

Problem	Possible cause	Action
No power to the unit when switched ON.	Power cable not connected properly.	Check power cable is fully connected.
	Fuse blown.	Check fuses and replace as necessary. Ensure the fuse drawer is pushed fully home following any maintenance checks or replacement.
	No power from power supply.	Check power supply.
Unit ON but poor / reduced fluid flow.	Tube not fitted to pump properly.	Check and fit tube to pump properly (Refer to “Preparation for use” on page 21).
	Endoscope tube kinked or blocked.	Replace with new tube.
	Tube kinked or blocked.	Replace with new tube.
	Flow setting is low.	Increase the flow setting.
	Pump head has deteriorated.	Measure the flow rate and replace with a new pump head if it is insufficient.
	Pump head lever has risen during pumping.	Replace with a new pump head.
Unit ON but no fluid flow.	Endoscope's auxiliary tube kinked or blocked.	Replace with a new auxiliary tube.
	Footswitch tube is disconnected, damaged or poorly fitted.	Check that the footswitch tube is fully connected.
	Fluid container empty.	Refill with sterile water.
	Tube kinked or blocked.	Replace with new tube.
	Tube not fitted to pump properly.	Check and fit tube to pump properly (Refer to “Preparation for use” on page 21).
	Endoscope blocked.	Check endoscope and correct.
	Endoscope tube kinked or blocked.	Replace with new tube.
	Incorrect tube fitted.	Check tubing and replace if necessary with specified tube (see Section “Consumable components” on page 14).
	Pump head has deteriorated and is unable to fill the endoscope with water within 20 seconds.	Flush while holding down the pump head lever with your finger.
	Pump head lever has risen during pumping.	Replace with a new pump head.
	Unit is in ‘standby mode’.	Make sure the pump head lever is closed and the unit is placed in ‘run mode’.

Unit ON, standby indicator flashes amber at a slow rate. All other functions are disabled.	Unit has sensed a motor overload and shut down.	Check for kinked tube, or damaged pump head or rollers (see above). To reset the overload cutout, switch off the mains power then switch on again.

Problem	Possible cause	Action
Remote control function not operating.	Remote control cable (MAJ-920) fitted incorrectly.	Check connection according to MAJ-920 instructions.
	Endoscope / video system center function set incorrectly.	Check endoscope / video system center settings according to manufacturer's instructions.
Fluid continues to flow without user activation.	Internal fault has occurred.	Turn OFF the unit's power supply and remove the tube from the endoscope or EndoTherapy device.
Interference to other equipment in the vicinity of the unit.	Magnetic - proximity of sensitive equipment to the pump motor’s magnetic field.	Relocate sensitive equipment to a higher shelf.
	Electrical - typically distortion/ interference on monitor display when equipment is operated.	Check system for damaged cables or connectors.
	Electromagnetic - interference from other systems.	As above, plus investigate source of interference.

Chapter 11 Technical description

The OFP-2 incorporates a brushless d.c. motor to drive the peristaltic pump head, producing high output torque with quiet operation. The control software monitors position sensors built into the motor to generate the commutating signals, forming a closed-loop feedback circuit which ensures excellent speed control over a wide range of motor loadings. These signals are boosted by the drive electronics to operate an 'H-bridge' mosfet output stage, with an overcurrent monitor to detect an overload on the motor, due, for example, to a damaged or poorly-fitted irrigation tube.

The control software also manages the display driving functions and the remote control interface on the rear panel which enables the unit to be operated via the buttons on a compatible endoscope.

The pump head incorporates a cutout switch to stop the motor if the cover is inadvertently raised without first selecting standby. This produces an interrupt to the software program and independently disables the drive electronics.

The electronics are powered by a 'universal input' medical-grade 24Vdc power supply. The mains input is connected through a double fused IEC appliance inlet containing an in-line EMC filter which also enables the unit to be isolated from the mains supply for cleaning, maintenance, etc. Power is controlled through a double pole push switch on the front panel.

A Maintenance and Repair Manual is available from Olympus containing circuit diagrams, parts lists, descriptions, replacement procedures and other information to assist qualified service personnel in repairing this equipment.

11.1 EMC (electromagnetic compatibility)

OFP-2 is EMC-tested in conformity with the requirements of IEC 60601-1-2:2014 Edition 4 and can be used in the vicinity of other EMC-tested devices that fulfil the requirements of the relevant IEC IEC 60601-1-2:2014 Edition 4 standard. OFP-2 is a medical device that requires special safety precautions and must be installed and placed in operation in accordance with the following EMC information on portable and mobile RF communication devices.

11.2 Essential performance with regards to EMC

Olympus has determined that OPF-2 does not have any functions, which if they failed to work properly, would impact the safety of the system. All necessary instruction for maintaining essential performance with regard to electromagnetic disturbances for the expected service life of the unit is listed in this chapter.

11.3 EMC environment

The OPF-2 is suitable for the professional health care facility environment as defined in IEC 60601-1-2:2014 Edition 4. In addition to this, the OPF-2 can operate near Olympus endoscopic HF surgical equipment outside a RF shielded room. Therefore, for this purpose only, the OPF-2 is suitable for the special environment as defined IEC 60601-1-2:2014 Edition 4. For maintaining basic safety and essential performance with regard to electromagnetic disturbances use only

Olympus specified parts.

WARNING

- Use of this equipment adjacent to or stacked with non-Olympus equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the OFP- 2 including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

NOTE

The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orientating the equipment.

11.4 Electromagnetic emissions

The OPF-2 intended for use in the electromagnetic environment specified below. The customer or the user of the OPF-2 should assure that it is used in such environment.

Emission tests compliance	**Level**
RF emissions CISPR 11	Group 1 Class A
Harmonic emissions IEC 61000-3-2:2018	Class A
Voltage fluctuations/flicker emissions IEC 60000-3-3:2013 and AMDI:2017	Complies

11.5 Electromagnetic immunity

The OPF-2 is intended for use in the electromagnetic environment specified below. The customer or the user of the OPF-2 should assure that it is used in such environment.

Immunity	**IEC 60601 test level**
Electrostatic Discharge (ESD) IEC601000-4-2:2008	± 8 kV contact, indirect ± 15 kV air
Electrical fast transient/burst IEC 61000-4-4:2012	± 2 kV for power supply lines ± 1 kV for input/output lines
Surge IEC 61000-4-5:2014	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11:2004 + AMD1:2017	1) 0% UT , 1 cycle 2) 0% UT , ½ cycle, Phase 0,45,90,135,180,225,270,315 3) 70% UT, (30% dip on UT for 25 cycles) 4) 0% UT for 5 sec
Conducted RF IEC 61000-4-6:2003 + A1:2004 + A2:2006	6 Vrms ISM bands 3 Vrms 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3:2006 + AMD1:2007 + AMD2:2010	3 V/m 80 MHz to 2.7 GHz IEC 60601-1-2:Ed 4 Table 9 bands/levels/modulations.

11.6 Accessories, transducers and cables

WARNING

Use of accessories, transducers and cables other than those specified in this document could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Chapter 12 End of Life

Equipment which reached end of its useful life must be decontaminated to local regulations before disposal and disposed of according to local regulations. OFP-2 should be dismantled and disposed of in accordance with local, state, national or federal laws. Refer to “Specification” on page 51 for additional information.

1. Remove Cover by unscrewing top fixing screws (x4).
2. Remove Pump Head.
3. Remove Motor & Gearbox by unscrewing front fixing screws (x3).
4. Remove PCB's and internal cabling.

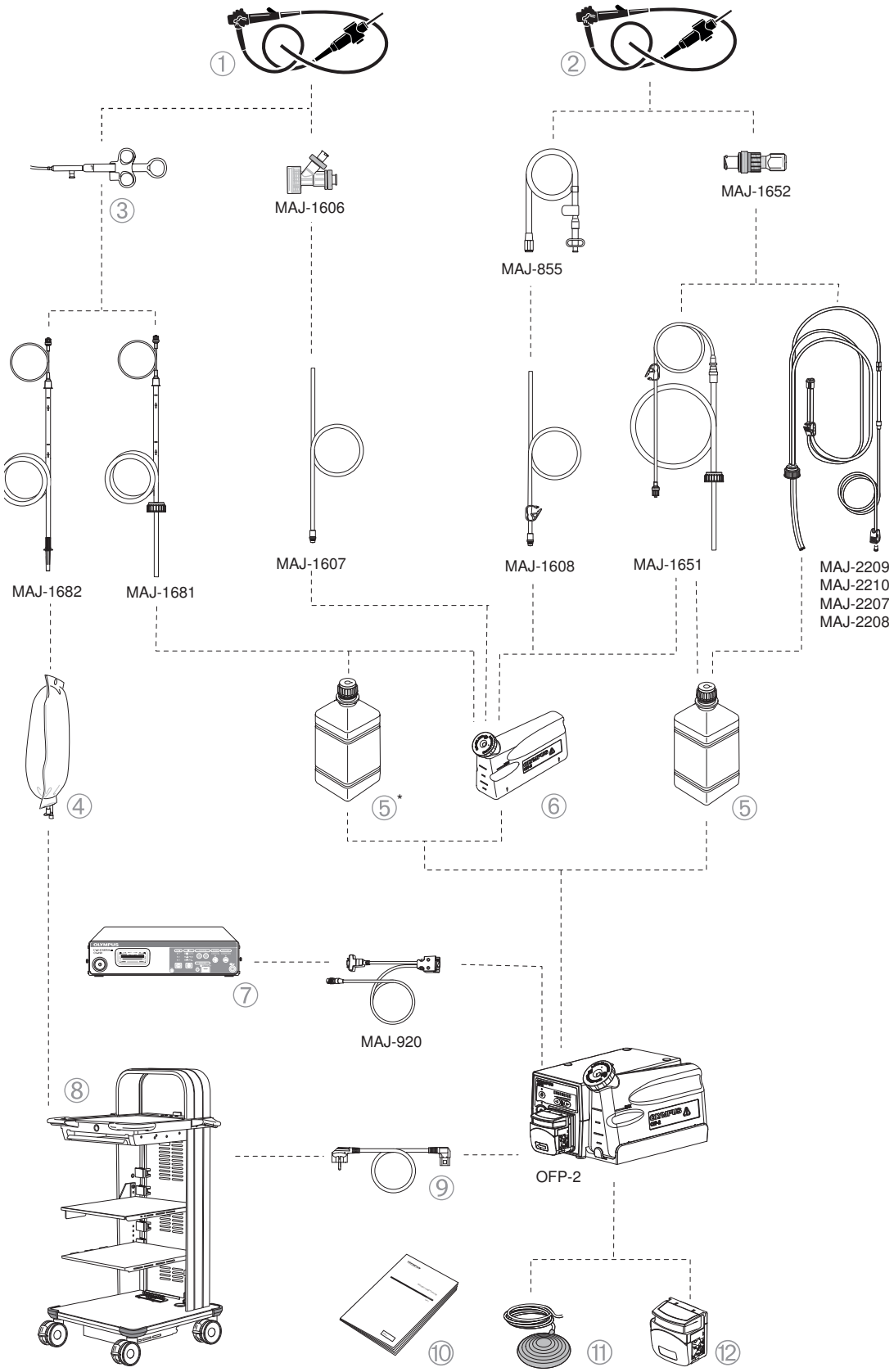
Appendix

System chart

The recommended combinations of equipment that can be used with the OFP-2 are shown overleaf. New products released after the introduction of the OFP-2 may also be compatible for use in combination with it. Contact your Olympus representative for further information on compatible products.

WARNING

If combinations of equipment are used, other than those shown overleaf, the full responsibility should be assumed by the medical treatment facility. Such combinations do not only not allow the equipment to manifest their full functionality but may also compromise the safety of the patient and medical personnel. In addition, the endurance of the OFP-2 and ancillary equipment is not guaranteed. Problems caused in this case are not covered by free-of-charge repair. Be sure to use the equipment in one of the recommended combinations.


①
②
③
MAJ-1606
MAJ-855
MAJ-1652
MAJ-1682
MAJ-1681
MAJ-1607
MAJ-1608
MAJ-1651
MAJ-2209
MAJ-2210
MAJ-2207
MAJ-2208
④
⑤*
⑥
⑤
⑦
MAJ-920
⑧
⑨
OFP-2
⑩
⑪
⑫

1. Compatible endoscopes when used with biopsy channel or compatible video ultrasound Endoscopes.
2. Compatible endoscopes when used with auxiliary channel.
3. Compatible FKD knives (not for use in conjunction with MAJ-1606)
4. Saline bag
5. Compatible disposable bottles
   (*saline bottles only)
6. MAJ-1603 2l water container
7. Compatible video system center
8. Compatible workstations and compact trollies
9. Power cable
10. Instructions for use
11. Pneumatic bellow foot switch
12. OPF-2 pump head

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